APPENDIX C

APPENDIX C

EXHIBITS INCORPORATED BY REFERENCE INTO INFORMATION QUALITY ACT REQUESTS FOR CORRECTION

TABLE OF CONTENTS

1. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 Fed. Reg. 8452 (February 22, 2002)
2. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, EPA, EPA/260R-02-008 October 2002 (Excerpts)
3. EPA website, *available at* http://www.epa.gov/IRIS/
4. Correspondence: February 21, 2012 and October 24, 2012 letters from Monica Jones, Director, Quality Staff, Office of Environmental Information, EPA, to Gregory Dolan, Executive Director-Americas/Europe, Methanol Institute (regarding IRIS Toxicological Review of Methanol); and October 24, 2012 and June 8, 2011 letters from Monica Jones, EPA, to Lynn Bergeson, Managing Director, Bergeson & Campbell, P.C. (regarding IRIS Toxicological Review of Inorganic Arsenic)
5. "Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde," National Research Council of the National Academies, April 2011 ("NAS Formaldehyde Peer Review Report") (Excerpts)
6. Toxicological Review of Libby Amphibole Asbestos, August 2011 External Review Draft (Excerpts)
7. http://www.epa.gov/risk/health-risk.htm and http://epa.gov/riskassessment/basicinformation.htm#arisk
8. December 16, 2013, A. Schmitt, U.S. Dept. of Justice, email
9. Treasury and General Government Appropriations Act for Fiscal Year 2001, Public Law 106–554, H.R. 5658, Section 515(a)
10. Testimony of EPA Administrator McCarthy Before the House Committee on Science, Space, and Technology, November 14, 2013
11. Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry, EPA, EPA/600/8-90/066F, October 1994 (Excerpts)
12. Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual, Part F (Supplemental Guidance for Inhalation Risk Assessment) Final, EPA/540/R/070/002, January 2009 (Excerpts)
13. A Review of the Reference Dose and Reference Concentration Processes, Final Report, EPA/630/P-02/002F, December 2002 (Excerpts)
14. Science Advisory Board Review of EPA's Draft Assessment entitled *Toxicological Review of Libby Amphibole Asbestos,* January 30, 2013 (Excerpts)

15. May 1, 2012 transcript of SAB panel (Excerpts)
16. June 27, 2012, SAB email
17. July 28, 2012, SAB email
18. February 6, 2012 transcript of SAB panel (Excerpts)
19. July 25, 2012 transcript of SAB panel (Excerpts)
20. Draft Science Advisory Board Report, April 2012 (Excerpts)
21. EPA Materials Submitted to the National Research Council Part I: Status of Implementation of Recommendations, January 30, 2013 (Excerpts)
22. October 12, 2012, SAB email
23. "Do Asbestos-Induced Pleural Plaques Cause Lung Function Deficits?" LE Kerper, HN Lynch, LC Mohr, JE Goodman, Society of Toxicology Poster, to be presented 2014
24. U.S. DOT/RITA/Volpe Center Contract, May 4, 2009 (Excerpts)
25. EPA Response to Draft Office of Inspector General Report, September 5, 2012 (Excerpts)
26. Appendix (p. A-74) to EPA's Response to Selected Major Interagency Comments on the Interagency Science Consultation Draft IRIS Toxicological Review of Libby Amphibole Asbestos, August 25, 2011(Office of Management and Budget questions related to the proposed RfC being below background levels)
27. EPA website, *available at* http://www.epa.gov/risk/exposure.htm, Step 3
28. Draft Phase V Sampling and Analysis Plan for Operable Unit 3, Libby Asbestos Superfund Site, Working Draft, March 20, 2012 (Excerpts)
29. May 30, 2013, email from Bill Brattin (SRC Inc.) to T. Hilbert copying Bob Benson (EPA) and David Berry (EPA); earlier May 17, 2013 emails between Bill Brattin (SRC Inc.) and T. Hilbert, copying Bob Benson; November 9, 2010, email from T. Hilbert to Bob Benson
30. April 23, 2010, email from Bob Benson to J. Hilbert and David Berry (EPA) and transmitted comments by Bob Benson

APPENDIX C – 1

OFFICE OF MANAGEMENT AND BUDGET

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication

Editorial Note: Due to numerous errors, this document is being reprinted in its entirety. It was originally printed in the **Federal Register** on Thursday, January 3, 2002 at 67 FR 369–378 and was corrected on Tuesday, February 5, 2002 at 67 FR 5365.

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Final guidelines.

SUMMARY: These final guidelines implement section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106–554; H.R. 5658). Section 515 directs the Office of Management and Budget (OMB) to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies." By October 1, 2002, agencies must issue their own implementing guidelines that include "administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency" that does not comply with the OMB guidelines. These final guidelines also reflect the changes OMB made to the guidelines issued September 28, 2001, as a result of receiving additional comment on the "capable of being substantially reproduced" standard (paragraphs V.3.B, V.9, and V.10), which OMB previously issued on September 28, 2001, on an interim final basis.

DATES: *Effective Date:* January 3, 2002.

FOR FURTHER INFORMATION CONTACT: Brooke J. Dickson, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Telephone (202) 395–3785 or by e-mail to informationquality@omb.eop.gov.

SUPPLEMENTARY INFORMATION: In section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106–554; H.R. 5658), Congress directed the Office of Management and Budget (OMB) to issue, by September 30, 2001, government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies * * *" Section 515(b) goes on to state that the OMB guidelines shall:

"(1) apply to the sharing by Federal agencies of, and access to, information disseminated by Federal agencies; and

"(2) require that each Federal agency to which the guidelines apply—

"(A) issue guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by the agency, by not later than 1 year after the date of issuance of the guidelines under subsection (a);

"(B) establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the guidelines issued under subsection (a); and

"(C) report periodically to the Director—

"(i) the number and nature of complaints received by the agency regarding the accuracy of information disseminated by the agency and;

"(ii) how such complaints were handled by the agency."

Proposed guidelines were published in the **Federal Register** on June 28, 2001 (66 FR 34489). Final guidelines were published in the **Federal Register** on September 28, 2001 (66 FR 49718). The Supplementary Information to the final guidelines published in September 2001 provides background, the underlying principles OMB followed in issuing the final guidelines, and statements of intent concerning detailed provisions in the final guidelines.

In the final guidelilnes published in September 2001, OMB also requested additional comment on the "capable of being substantially reproduced" standard and the related definition of "influential scientific or statistical information" (paragraphs V.3.B, V.9, and V.10), which were issued on an interim final basis. The final guidelines published today discuss the public comments OMB received, the OMB response, and amendments to the final guidelines published in September 2001.

In developing agency-specific guidelines, agencies should refer both to the Supplementary Information to the final guidelines published in the **Federal Register** on September 28, 2001 (66 FR 49718), and also to the Supplementary Information published today. We stress that the three "Underlying Principles" that OMB followed in drafting the guidelines that we published on September 28, 2001 (66 FR 49719), are also applicable to the amended guidelines that we publish today.

In accordance with section 515, OMB has designed the guidelines to help agencies ensure and maximize the quality, utility, objectivity and integrity of the information that they disseminate (meaning to share with, or give access to, the public). It is crucial that information Federal agencies disseminate meets these guidelines. In this respect, the fact that the Internet enables agencies to communicate information quickly and easily to a wide audience not only offers great benefits to society, but also increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines. Recognizing the wide variety of information Federal agencies disseminate and the wide variety of dissemination practices that agencies have, OMB developed the guidelines with several principles in mind.

First, OMB designed the guidelines to apply to a wide variety of government information dissemination activities that may range in importance and scope. OMB also designed the guidelines to be generic enough to fit all media, be they printed, electronic, or in other form. OMB sought to avoid the problems that would be inherent in developing detailed, prescriptive, "one-size-fits-all" government-wide guidelines that would artificially require different types of dissemination activities to be treated in the same manner. Through this flexibility, each agency will be able to incorporate the requirements of these OMB guidelines into the agency's own information resource management and administrative practices.

Second, OMB designed the guidelines so that agencies will meet basic information quality standards. Given the administrative mechanisms required by section 515 as well as the standards set forth in the Paperwork Reduction Act, it is clear that agencies should not disseminate substantive information that does not meet a basic level of quality. We recognize that some government information may need to meet higher or more specific information quality standards than those that would apply to other types of government information. The more important the information, the higher the quality standards to which it should be held, for example, in those situations involving "influential scientific, financial, or statistical information" (a phrase defined in these guidelines). The guidelines recognize, however, that

information quality comes at a cost. Accordingly, the agencies should weigh the costs (for example, including costs attributable to agency processing effort, respondent burden, maintenance of needed privacy, and assurances of suitable confidentiality) and the benefits of higher information quality in the development of information, and the level of quality to which the information disseminated will be held.

Third, OMB designed the guidelines so that agencies can apply them in a common-sense and workable manner. It is important that these guidelines do not impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other technologies to disseminate information that can be of great benefit and value to the public. In this regard, OMB encourages agencies to incorporate the standards and procedures required by these guidelines into their existing information resources management and administrative practices rather than create new and potentially duplicative or contradictory processes. The primary example of this is that the guidelines recognize that, in accordance with OMB Circular A–130, agencies already have in place well-established information quality standards and administrative mechanisms that allow persons to seek and obtain correction of information that is maintained and disseminated by the agency. Under the OMB guidelines, agencies need only ensure that their own guidelines are consistent with these OMB guidelines, and then ensure that their administrative mechanisms satisfy the standards and procedural requirements in the new agency guidelines. Similarly, agencies may rely on their implementation of the Federal Government's computer security laws (formerly, the Computer Security Act, and now the computer security provisions of the Paperwork Reduction Act) to establish appropriate security safeguards for ensuring the "integrity" of the information that the agencies disseminate.

In addition, in response to concerns expressed by some of the agencies, we want to emphasize that OMB recognizes that Federal agencies provide a wide variety of data and information. Accordingly, OMB understands that the guidelines discussed below cannot be implemented in the same way by each agency. In some cases, for example, the data disseminated by an agency are not collected by that agency; rather, the information the agency must provide in a timely manner is compiled from a variety of sources that are constantly updated and revised and may be confidential. In such cases, while agencies' implementation of the guidelines may differ, the essence of the guidelines will apply. That is, these agencies must make their methods transparent by providing documentation, ensure quality by reviewing the underlying methods used in developing the data and consulting (as appropriate) with experts and users, and keep users informed about corrections and revisions.

Summary of OMB Guidelines

These guidelines apply to Federal agencies subject to the Paperwork Reduction Act (44 U.S.C. chapter 35). Agencies are directed to develop information resources management procedures for reviewing and substantiating (by documentation or other means selected by the agency) the quality (including the objectivity, utility, and integrity) of information before it is disseminated. In addition, agencies are to establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of information disseminated by the agency that does not comply with the OMB or agency guidelines. Consistent with the underlying principles described above, these guidelines stress the importance of having agencies apply these standards and develop their administrative mechanisms so they can be implemented in a common sense and workable manner. Moreover, agencies must apply these standards flexibly, and in a manner appropriate to the nature and timeliness of the information to be disseminated, and incorporate them into existing agency information resources management and administrative practices.

Section 515 denotes four substantive terms regarding information disseminated by Federal agencies: quality, utility, objectivity, and integrity. It is not always clear how each substantive term relates—or how the four terms in aggregate relate—to the widely divergent types of information that agencies disseminate. The guidelines provide definitions that attempt to establish a clear meaning so that both the agency and the public can readily judge whether a particular type of information to be disseminated does or does not meet these attributes.

In the guidelines, OMB defines "quality" as the encompassing term, of which "utility," "objectivity," and "integrity" are the constituents. "Utility" refers to the usefulness of the information to the intended users. "Objectivity" focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. "Integrity" refers to security—the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. OMB modeled the definitions of "information," "government information," "information dissemination product," and "dissemination" on the longstanding definitions of those terms in OMB Circular A–130, but tailored them to fit into the context of these guidelines.

In addition, Section 515 imposes two reporting requirements on the agencies. The first report, to be promulgated no later than October 1, 2002, must provide the agency's information quality guidelines that describe administrative mechanisms allowing affected persons to seek and obtain, where appropriate, correction of disseminated information that does not comply with the OMB and agency guidelines. The second report is an annual fiscal year report to OMB (to be first submitted on January 1, 2004) providing information (both quantitative and qualitative, where appropriate) on the number, nature, and resolution of complaints received by the agency regarding its perceived or confirmed failure to comply with these OMB and agency guidelines.

Public Comments and OMB Response

Applicability of Guidelines. Some comments raised concerns about the applicability of these guidelines, particularly in the context of scientific research conducted by Federally employed scientists or Federal grantees who publish and communicate their research findings in the same manner as their academic colleagues. OMB believes that information generated and disseminated in these contexts is not covered by these guidelines unless the agency represents the information as, or uses the information in support of, an official position of the agency.

As a general matter, these guidelines apply to "information" that is "disseminated" by agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)). See paragraphs II, V.5 and V.8. The definitions of "information" and "dissemination" establish the scope of the applicability of these guidelines. "Information" means "any communication or representation of knowledge such as facts or data * * *" This definition of information in paragraph V.5 does "not include opinions, where the agency's presentation makes it clear that what is

being offered is someone's opinion rather than fact or the agency's views."

"Dissemination" is defined to mean "agency initiated or sponsored distribution of information to the public." As used in paragraph V.8, "agency INITIATED * * * distribution of information to the public" refers to information that the agency disseminates, e.g., a risk assessment prepared by the agency to inform the agency's formulation of possible regulatory or other action. In addition, if an agency, as an institution, disseminates information prepared by an outside party in a manner that reasonably suggests that the agency agrees with the information, this appearance of having the information represent agency views makes agency dissemination of the information subject to these guidelines. By contrast, an agency does not "initiate" the dissemination of information when a Federally employed scientist or Federal grantee or contractor publishes and communicates his or her research findings in the same manner as his or her academic colleagues, even if the Federal agency retains ownership or other intellectual property rights because the Federal government paid for the research. To avoid confusion regarding whether the agency agrees with the information (and is therefore disseminating it through the employee or grantee), the researcher should include an appropriate disclaimer in the publication or speech to the effect that the "views are mine, and do not necessarily reflect the view" of the agency.

Similarly, as used in paragraph V.8., "agency * * * SPONSORED distribution of information to the public" refers to situations where an agency has directed a third-party to disseminate information, or where the agency has the authority to review and approve the information before release. Therefore, for example, if an agency through a procurement contract or a grant provides for a person to conduct research, and then the agency directs the person to disseminate the results (or the agency reviews and approves the results before they may be disseminated), then the agency has "sponsored" the dissemination of this information. By contrast, if the agency simply provides funding to support research, and it the researcher (not the agency) who decides whether to disseminate the results and—if the results are to be released—who determines the content and presentation of the dissemination, then the agency has not "sponsored" the dissemination even though it has funded the research and even if the Federal agency retains ownership or other intellectual property rights because the Federal government paid for the research. To avoid confusion regarding whether the agency is sponsoring the dissemination, the researcher should include an appropriate disclaimer in the publication or speech to the effect that the "views are mine, and do not necessarily reflect the view" of the agency. On the other hand, subsequent agency dissemination of such information requires that the information adhere to the agency's information quality guidelines. In sum, these guidelines govern an agency's dissemination of information, but generally do not govern a third-party's dissemination of information (the exception being where the agency is essentially using the third-party to disseminate information on the agency's behalf). Agencies, particularly those that fund scientific research, are encouraged to clarify the applicability of these guidelines to the various types of information they and their employees and grantees disseminate.

Paragraph V.8 also states that the definition of "dissemination" does not include "* * * distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes." The exemption from the definition of "dissemination" for "adjudicative processes" is intended to exclude, from the scope of these guidelines, the findings and determinations that an agency makes in the course of adjudications involving specific parties. There are well-established procedural safeguards and rights to address the quality of adjudicatory decisions and to provide persons with an opportunity to contest decisions. These guidelines do not impose any additional requirements on agencies during adjudicative proceedings and do not provide parties to such adjudicative proceedings any additional rights of challenge or appeal.

*The Presumption Favoring Peer-Reviewed Information.*As a general matter, in the scientific and research context, we regard technical information that has been subjected to formal, independent, external peer review as presumptively objective. As the guidelines state in paragraph V.3.b.i: "If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity." An example of a formal, independent, external peer review is the review process used by scientific journals.

Most comments approved of the prominent role that peer review plays in the OMB guidelines. Some comments contended that peer review was not accepted as a universal standard that incorporates an established, practiced, and sufficient level of objectivity. Other comments stated that the guidelines would be better clarified by making peer review one of several factors that an agency should consider in assessing the objectivity (and quality in general) of original research. In addition, several comments noted that peer review does not establish whether analytic results are capable of being substantially reproduced. In light of the comments, the final guidelines in new paragraph V.3.b.i qualify the presumption in favor of peer-reviewed information as follows: "However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance."

We believe that transparency is important for peer review, and these guidelines set minimum standards for the transparency of agency-sponsored peer review. As we state in new paragraph V.3.b.i: "If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance. If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB–OIRA to the President's Management Council (9/20/01) (http://www.whitehouse.gov/omb/inforeg/oira_review-process.html), namely, 'that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner.'"

The importance of these general criteria for competent and credible peer review has been supported by a number of expert bodies. For example, "the work of fully competent peer-review panels can be undermined by allegations of conflict of interest and bias. Therefore, the best interests of the Board are served by effective policies and procedures regarding potential conflicts of interest, impartiality, and panel balance." (*EPA's Science Advisory*

Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, GAO–01–536, General Accounting Office, Washington, DC, June 2001, page 19.) As another example, "risk analyses should be peer-reviewed and accessible—both physically and intellectually—so that decision-makers at all levels will be able to respond critically to risk characterizations. The intensity of the peer reviews should be commensurate with the significance of the risk or its management implications." (*Setting Priorities, Getting Results: A New Direction for EPA,* Summary Report, National Academy of Public Administration, Washington, DC, April 1995, page 23.)

These criteria for peer reviewers are generally consistent with the practices now followed by the National Research Council of the National Academy of Sciences. In considering these criteria for peer reviewers, we note that there are many types of peer reviews and that agency guidelines concerning the use of peer review should tailor the rigor of peer review to the importance of the information involved. More generally, agencies should define their peer-review standards in appropriate ways, given the nature and importance of the information they disseminate.

Is Journal Peer Review Always Sufficient? Some comments argued that journal peer review should be adequate to demonstrate quality, even for influential information that can be expected to have major effects on public policy. OMB believes that this position overstates the effectiveness of journal peer review as a quality-control mechanism.

Although journal peer review is clearly valuable, there are cases where flawed science has been published in respected journals. For example, the NIH Office of Research Integrity recently reported the following case regarding environmental health research:

> "Based on the report of an investigation conducted by [XX] University, dated July 16, 1999, and additional analysis conducted by ORI in its oversight review, the US Public Health Service found that Dr. [X] engaged in scientific misconduct. Dr. [X] committed scientific misconduct by intentionally falsifying the research results published in the journal SCIENCE and by providing falsified and fabricated materials to investigating officials at [XX] University in response to a request for original data to support the research results and conclusions report in the SCIENCE paper. In addition, PHS finds that there is no original data or other corroborating evidence to support the research results and conclusions reported in the SCIENCE paper as a whole." (66 FR 52137, October 12, 2001).

Although such cases of falsification are presumably rare, there is a significant scholarly literature documenting quality problems with articles published in peer-reviewed research. "In a [peer-reviewed] meta-analysis that surprised many—and some doubt—researchers found little evidence that peer review actually improves the quality of research papers." (*See, e.g., Science,* Vol. 293, page 2187 (September 21, 2001.)) In part for this reason, many agencies have already adopted peer review and science advisory practices that go beyond journal peer review. *See, e.g.,* Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policy Makers,* Cambridge, MA, Harvard University Press, 1990; Mark R. Powell, *Science at EPA: Information in the Regulatory Process.* Resources for the Future, Washington, DC., 1999, pages 138–139; 151–153; *Implementation of the Environmental Protection Agency's Peer Review Program: An SAB Evaluation of Three Reviews,* EPA–SAB–RSAC–01–009, A Review of the Research Strategies Advisory Committee (RSAC) of the EPA Science Advisory Board (SAB), Washington, DC., September 26, 2001. For information likely to have an important public policy or private sector impact, OMB believes that additional quality checks beyond peer review are appropriate.

Definition of "Influential". OMB guidelines apply stricter quality standards to the dissemination of information that is considered "influential." Comments noted that the breadth of the definition of "influential" in interim final paragraph V.9 requires much speculation on the part of agencies.

We believe that this criticism has merit and have therefore narrowed the definition. In this narrower definition, "influential", when used in the phrase "influential scientific, financial, or statistical information", is amended to mean that "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." The intent of the new phrase "clear and substantial" is to reduce the need for speculation on the part of agencies. We added the present tense—"or does have"—to this narrower definition because on occasion, an information dissemination may occur simultaneously with a particular policy change. In response to a public comment, we added an explicit reference to "financial" information as consistent with our original intent.

Given the differences in the many Federal agencies covered by these guidelines, and the differences in the nature of the information they disseminate, we also believe it will be helpful if agencies elaborate on this definition of "influential" in the context of their missions and duties, with due consideration of the nature of the information they disseminate. As we state in amended paragraph V.9, "Each agency is authorized to define 'influential' in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible."

Reproducibility. As we state in new paragraph V.3.b.ii: "If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties." OMB believes that a reproducibility standard is practical and appropriate for information that is considered "influential", as defined in paragraph V.9—that "will have or does have a clear and substantial impact on important public policies or important private sector decisions." The reproducibility standard applicable to influential scientific, financial, or statistical information is intended to ensure that information disseminated by agencies is sufficiently transparent in terms of data and methods of analysis that it would be feasible for a replication to be conducted. The fact that the use of original and supporting data and analytic results have been deemed "defensible" by peer-review procedures does not necessarily imply that the results are transparent and replicable.

Reproducibility of Original and Supporting Data. Several of the comments objected to the exclusion of original and supporting data from the reproducibility requirements. Comments instead suggested that OMB should apply the reproducibility standard to original data, and that OMB should provide flexibility to the agencies in determining what constitutes "original and supporting" data. OMB agrees and asks that agencies consider, in developing their own guidelines, which categories of original and supporting data should be subject to the reproducibility standard and which should not. To help in resolving this issue, we also ask agencies to consult directly with relevant scientific and technical communities on the feasibility of having the selected categories of original and supporting data subject to the reproducibility standard. Agencies are encouraged to address ethical, feasibility, and confidentiality issues

with care. As we state in new paragraph V.3.b.ii.A, "Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints." Further, as we state in our expanded definition of "reproducibility" in paragraph V.10, "If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (*e.g.*, standards for replication of laboratory data)." OMB urges caution in the treatment of original and supporting data because it may often be impractical or even impermissible or unethical to apply the reproducibility standard to such data. For example, it may not be ethical to repeat a "negative" (ineffective) clinical (therapeutic) experiment and it may not be feasible to replicate the radiation exposures studied after the Chernobyl accident. When agencies submit their draft agency guidelines for OMB review, agencies should include a description of the extent to which the reproducibility standard is applicable and reflect consultations with relevant scientific and technical communities that were used in developing guidelines related to applicability of the reproducibility standard to original and supporting data.

It is also important to emphasize that the reproducibility standard does not apply to all original and supporting data disseminated by agencies. As we state in new paragraph V.3.b.ii.A, "With regard to original and supporting data related [to influential scientific, financial, or statistical information], agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement." In addition, we encourage agencies to address how greater transparency can be achieved regarding original and supporting data. As we also state in new paragraph V.3.b.ii.A, "It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (*i.e.*, a new experiment, test, or sample) shall not be required prior to each dissemination." Agency guidelines need to achieve a high degree of transparency about data even when reproducibility is not required.

Reproducibility of Analytic Results. Many public comments were critical of the reproducibility standard and expressed concern that agencies would be required to reproduce each analytical result before it is disseminated. While several comments commended OMB for establishing an appropriate balance in the "capable of being substantially reproduced" standard, others considered this standard to be inherently subjective. There were also comments that suggested the standard would cause more burden for agencies.

It is not OMB's intent that each agency must reproduce each analytic result before it is disseminated. The purpose of the reproducibility standard is to cultivate a consistent agency commitment to transparency about how analytic results are generated: the specific data used, the various assumptions employed, the specific analytic methods applied, and the statistical procedures employed. If sufficient transparency is achieved on each of these matters, then an analytic result should meet the "capable of being substantially reproduced" standard.

While there is much variation in types of analytic results, OMB believes that reproducibility is a practical standard to apply to most types of analytic results. As we state in new paragraph V.3.b.ii.B, "With regard to analytic results related [to influential scientific, financial, or statistical information], agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies." We elaborate upon this principle in our expanded definition of "reproducibility" in paragraph V.10: "With respect to analytic results, 'capable of being substantially reproduced' means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error."

Even in a situation where the original and supporting data are protected by confidentiality concerns, or the analytic computer models or other research methods may be kept confidential to protect intellectual property, it may still be feasible to have the analytic results subject to the reproducibility standard. For example, a qualified party, operating under the same confidentiality protections as the original analysts, may be asked to use the same data, computer model or statistical methods to replicate the analytic results reported in the original study. *See, e.g.*, "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality," A Special Report of the Health Effects Institute's Particle Epidemiology Reanalysis Project, Cambridge, MA, 2000.

The primary benefit of public transparency is not necessarily that errors in analytic results will be detected, although error correction is clearly valuable. The more important benefit of transparency is that the public will be able to assess how much an agency's analytic result hinges on the specific analytic choices made by the agency. Concreteness about analytic choices allows, for example, the implications of alternative technical choices to be readily assessed. This type of sensitivity analysis is widely regarded as an essential feature of high-quality analysis, yet sensitivity analysis cannot be undertaken by outside parties unless a high degree of transparency is achieved. The OMB guidelines do not compel such sensitivity analysis as a necessary dimension of quality, but the transparency achieved by reproducibility will allow the public to undertake sensitivity studies of interest.

We acknowledge that confidentiality concerns will sometimes preclude public access as an approach to reproducibility. In response to public comment, we have clarified that such concerns do include interests in "intellectual property." To ensure that the OMB guidelines have sufficient flexibility with regard to analytic transparency, OMB has, in new paragraph V.3.b.ii.B.i, provided agencies an alternative approach for classes or types of analytic results that cannot practically be subject to the reproducibility standard. "[In those situations involving influential scientific, financial, or statistical information * * *] making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections." Specifically, in cases where reproducibility will not occur due to other compelling interests, we expect agencies (1) to perform robustness checks appropriate to the importance of the information involved, e.g., determining whether a specific statistic is sensitive to the choice of analytic method, and, accompanying the information disseminated, to document their efforts to assure the needed robustness in information quality, and (2) address in their guidelines the

degree to which they anticipate the opportunity for reproducibility to be limited by the confidentiality of underlying data. As we state in new paragraph V.3.b.ii.B.*ii*, "In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken. Agency guidelines shall, however, in all cases, require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed."

Given the differences in the many Federal agencies covered by these guidelines, and the differences in robustness checks and the level of detail for documentation thereof that might be appropriate for different agencies, we also believe it will be helpful if agencies elaborate on these matters in the context of their missions and duties, with due consideration of the nature of the information they disseminate. As we state in new paragraph V.3.b.ii.B.ii, "Each agency is authorized to define the type of robustness checks, and the level of detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible."

We leave the determination of the appropriate degree of rigor to the discretion of agencies and the relevant scientific and technical communities that work with the agencies. We do, however, establish a general standard for the appropriate degree of rigor in our expanded definition of "reproducibility" in paragraph V.10: " 'Reproducibility' means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased)." OMB will review each agency's treatment of this issue when reviewing the agency guidelines as a whole.

Comments also expressed concerns regarding interim final paragraph V.3.B.iii, "making the data and models publicly available will assist in determining whether analytic results are capable of being substantially reproduced," and whether it could be interpreted to constitute public dissemination of these materials, rendering moot the reproducibility test. (For the equivalent provision, see new paragraph V.3.b.ii.B.*i*.) The OMB guidelines do not require agencies to reproduce each disseminated analytic result by independent reanalysis. Thus, public dissemination of data and models *per se* does not mean that the analytic result has been reproduced. It means only that the result should be CAPABLE of being reproduced. The transparency associated with this capability of reproduction is what the OMB guidelines are designed to achieve.

We also want to build on a general observation that we made in our final guidelines published in September 2001. In those guidelines we stated: "... in those situations involving influential scientific[, financial,] or statistical information, the substantial reproducibility standard is added as a quality standard above and beyond some peer review quality standards" (66 FR 49722 (September 28, 2001)). A hypothetical example may serve to illustrate this point. Assume that two Federal agencies initiated or sponsored the dissemination of five scientific studies after October 1, 2002 (see paragraph III.4) that were, before dissemination, subjected to formal, independent, external peer review, i.e., that met the presumptive standard for "objectivity" under paragraph V.3.b.i. Further assume, at the time of dissemination, that neither agency reasonably expected that the dissemination of any of these studies would have "a clear and substantial impact" on important public policies, *i.e.*, that these studies were not considered "influential" under paragraph V.9, and thus not subject to the reproducibility standards in paragraphs V.3.b.ii.A or B. Then assume, two years later, in 2005, that one of the agencies decides to issue an important and far-reaching regulation based clearly and substantially on the agency's evaluation of the analytic results set forth in these five studies and that such agency reliance on these five studies as published in the agency's notice of proposed rulemaking would constitute dissemination of these five studies. These guidelines would require the rulemaking agency, prior to publishing the notice of proposed rulemaking, to evaluate these five studies to determine if the analytic results stated therein would meet the "capable of being substantially reproduced" standards in paragraph V.3.b.ii.B and, if necessary, related standards governing original and supporting data in paragraph V.3.b.ii.A. If the agency were to decide that any of the five studies would not meet the reproducibility standard, the agency may still rely on them but only if they satisfy the transparency standard and—as applicable—the disclosure of robustness checks required by these guidelines. Otherwise, the agency should not disseminate any of the studies that did not meet the applicable standards in the guidelines at the time it publishes the notice of proposed rulemaking.

Some comments suggested that OMB consider replacing the reproducibility standard with a standard concerning "confirmation" of results for influential scientific and statistical information. Although we encourage agencies to consider "confirmation" as a relevant standard—at least in some cases—for assessing the objectivity of original and supporting data, we believe that "confirmation" is too stringent a standard to apply to analytic results. Often the regulatory impact analysis prepared by an agency for a major rule, for example, will be the only formal analysis of an important subject. It would be unlikely that the results of the regulatory impact analysis had already been confirmed by other analyses. The "capable of being substantially reproduced" standard is less stringent than a "confirmation" standard because it simply requires that an agency's analysis be sufficiently transparent that another qualified party could replicate it through reanalysis.

Health, Safety, and Environmental Information. We note, in the scientific context, that in 1996 the Congress, for health decisions under the Safe Drinking Water Act, adopted a basic standard of quality for the use of science in agency decisionmaking. Under 42 U.S.C. 300g–1(b)(3)(A), an agency is directed, "to the degree that an Agency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."

We further note that in the 1996 amendments to the Safe Drinking Water Act, Congress adopted a basic quality standard for the dissemination of public information about risks of adverse health effects. Under 42 U.S.C. 300g–1(b)(3)(B), the agency is directed, "to ensure that the presentation of information [risk] effects is comprehensive, informative, and understandable." The agency is further directed, "in a document made available to the public in support of a regulation [to] specify, to the extent practicable—(i) each population addressed by any estimate [of applicable risk effects]; (ii) the expected risk or central estimate of

risk for the specific populations [affected]; (iii) each appropriate upper-bound or lower-bound estimate of risk; (iv) each significant uncertainty identified in the process of the assessment of [risk] effects and the studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the [agency] that support, are directly relevant to, or fail to support any estimate of [risk] effects and the methodology used to reconcile inconsistencies in the scientific data."

As suggested in several comments, we have included these congressional standards directly in new paragraph V.3.b.ii.C, and made them applicable to the information disseminated by all the agencies subject to these guidelines: "With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g–1(b)(3)(A) & (B))." The word "adapt" is intended to provide agencies flexibility in applying these principles to various types of risk assessment.

Comments also argued that the continued flow of vital information from agencies responsible for disseminating health and medical information to medical providers, patients, and the public may be disrupted due to these peer review and reproducibility standards. OMB responded by adding to new paragraph V.3.b.ii.C: "Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (*e.g.*, imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines."

Administrative Correction Mechanisms. In addition to commenting on the substantive standards in these guidelines, many of the comments noted that the OMB guidelines on the administrative correction of information do not specify a time period in which the agency investigation and response must be made. OMB has added the following new paragraph III.3.i to direct agencies to specify appropriate time periods in which the investigation and response need to be made. "Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made."

Several comments stated that the OMB guidelines needed to direct agencies to consider incorporating an administrative appeal process into their administrative mechanisms for the correction of information. OMB agreed, and added the following new paragraph III.3.ii: "If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration." Recognizing that many agencies already have a process in place to respond to public concerns, it is not necessarily OMB's intent to require these agencies to establish a new or different process. Rather, our intent is to ensure that agency guidelines specify an objective administrative appeal process that, upon furthercomplaint by the affected person, reviews an agency's decision to disagree with the correction request. An objective process will ensure that the office that originally disseminates the information does not have responsibility for both the initial response and resolution of a disagreement. In addition, the agency guidelines should specify that if the agency believes other agencies may have an interest in the resolution of any administrative appeal, the agency should consult with those other agencies about their possible interest.

Overall, OMB does not envision administrative mechanisms that would burden agencies with frivolous claims. Instead, the correction process should serve to address the genuine and valid needs of the agency and its constituents without disrupting agency processes. Agencies, in making their determination of whether or not to correct information, may reject claims made in bad faith or without justification, and are required to undertake only the degree of correction that they conclude is appropriate for the nature and timeliness of the information involved, and explain such practices in their annual fiscal year reports to OMB.

OMB's issuance of these final guidelines is the beginning of an evolutionary process that will include draft agency guidelines, public comment, final agency guidelines, development of experience with OMB and agency guidelines, and continued refinement of both OMB and agency guidelines. Just as OMB requested public comment before issuing these final guidelines, OMB will refine these guidelines as experience develops and further public comment is obtained.

Dated: December 21, 2001.

John D. Graham,

Administrator, Office of Information and Regulatory Affairs.

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

I. OMB Responsibilities

Section 515 of the Treasury and General Government Appropriations Act for FY2001 (Public Law 106–554) directs the Office of Management and Budget to issue government-wide guidelines that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies.

II. Agency Responsibilities

Section 515 directs agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)) to—

1. Issue their own information quality guidelines ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency no later than one year after the date of issuance of the OMB guidelines;

2. Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with these OMB guidelines; and

3. Report to the Director of OMB the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines concerning the quality, objectivity, utility, and integrity of information and how such complaints were resolved.

III. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies

1. Overall, agencies shall adopt a basic standard of quality (including objectivity, utility, and integrity) as a performance goal and should take appropriate steps to incorporate information quality criteria into agency information dissemination practices. Quality is to be ensured and established at levels appropriate to the nature and timeliness of the information to be disseminated. Agencies shall adopt

specific standards of quality that are appropriate for the various categories of information they disseminate.

2. As a matter of good and effective agency information resources management, agencies shall develop a process for reviewing the quality (including the objectivity, utility, and integrity) of information before it is disseminated. Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination. This process shall enable the agency to substantiate the quality of the information it has disseminated through documentation or other means appropriate to the information.

3. To facilitate public review, agencies shall establish administrative mechanisms allowing affected persons to seek and obtain, where appropriate, timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines. These administrative mechanisms shall be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into agency information resources management and administrative practices.

i. Agencies shall specify appropriate time periods for agency decisions on whether and how to correct the information, and agencies shall notify the affected persons of the corrections made.

ii. If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any), the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision, and specify appropriate time limits in which to resolve such requests for reconsideration.

4. The agency's pre-dissemination review, under paragraph III.2, shall apply to information that the agency first disseminates on or after October 1, 2002. The agency's administrative mechanisms, under paragraph III.3., shall apply to information that the agency disseminates on or after October 1, 2002, regardless of when the agency first disseminated the information.

IV. Agency Reporting Requirements

1. Agencies must designate the Chief Information Officer or another official to be responsible for agency compliance with these guidelines.

2. The agency shall respond to complaints in a manner appropriate to the nature and extent of the complaint. Examples of appropriate responses include personal contacts via letter or telephone, form letters, press releases or mass mailings that correct a widely disseminated error or address a frequently raised complaint.

3. Each agency must prepare a draft report, no later than April 1, 2002, providing the agency's information quality guidelines and explaining how such guidelines will ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by the agency. This report must also detail the administrative mechanisms developed by that agency to allow affected persons to seek and obtain appropriate correction of information maintained and disseminated by the agency that does not comply with the OMB or the agency guidelines.

4. The agency must publish a notice of availability of this draft report in the **Federal Register**, and post this report on the agency's website, to provide an opportunity for public comment.

5. Upon consideration of public comment and after appropriate revision, the agency must submit this draft report to OMB for review regarding consistency with these OMB guidelines no later than July 1, 2002. Upon completion of that OMB review and completion of this report, agencies must publish notice of the availability of this report in its final form in the **Federal Register**, and post this report on the agency's web site no later than October 1, 2002.

6. On an annual fiscal-year basis, each agency must submit a report to the Director of OMB providing information (both quantitative and qualitative, where appropriate) on the number and nature of complaints received by the agency regarding agency compliance with these OMB guidelines and how such complaints were resolved. Agencies must submit these reports no later than January 1 of each following year, with the first report due January 1, 2004.

V. Definitions

1. "Quality" is an encompassing term comprising utility, objectivity, and integrity. Therefore, the guidelines sometimes refer to these four statutory terms, collectively, as "quality."

2. "Utility" refers to the usefulness of the information to its intended users, including the public. In assessing the usefulness of information that the agency disseminates to the public, the agency needs to consider the uses of the information not only from the perspective of the agency but also from the perspective of the public. As a result, when transparency of information is relevant for assessing the information's usefulness from the public's perspective, the agency must take care to ensure that transparency has been addressed in its review of the information.

3. "Objectivity" involves two distinct elements, presentation and substance.

a. "Objectivity" includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes, in disseminating certain types of information to the public, other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information (to the extent possible, consistent with confidentiality protections) and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.

b. In addition, "objectivity" involves a focus on ensuring accurate, reliable, and unbiased information. In a scientific, financial, or statistical context, the original and supporting data shall be generated, and the analytic results shall be developed, using sound statistical and research methods.

i. If data and analytic results have been subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption is rebuttable based on a persuasive showing by the petitioner in a particular instance. If agency-sponsored peer review is employed to help satisfy the objectivity standard, the review process employed shall meet the general criteria for competent and credible peer review recommended by OMB–OIRA to the President's Management Council (9/20/01) (http://www.whitehouse.gov/omb/inforeg/oira_review-process.html), namely, "that (a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand, (c) peer reviewers be expected to disclose to agencies their sources of personal and

institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner."

ii. If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties.

A. With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicable be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints. It is understood that reproducibility of data is an indication of transparency about research design and methods and thus a replication exercise (i.e., a new experiment, test, or sample) shall not be required prior to each dissemination.

B. With regard to analytic results related thereto, agency guidelines shall generally require sufficient transparency about data and methods that an independent reanalysis could be undertaken by a qualified member of the public. These transparency standards apply to agency analysis of data from a single study as well as to analyses that combine information from multiple studies.

i. Making the data and methods publicly available will assist in determining whether analytic results are reproducible. However, the objectivity standard does not override other compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections.

ii. In situations where public access to data and methods will not occur due to other compelling interests, agencies shall apply especially rigorous robustness checks to analytic results and document what checks were undertaken. Agency guidelines shall, however, in all cases, require a disclosure of the specific data sources that have been used and the specific quantitative methods and assumptions that have been employed. Each agency is authorized to define the type of robustness checks, and the level of detail for documentation thereof, in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

C. With regard to analysis of risks to human health, safety and the environment maintained or disseminated by the agencies, agencies shall either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the Safe Drinking Water Act Amendments of 1996 (42 U.S.C. 300g–1(b)(3)(A) & (B)). Agencies responsible for dissemination of vital health and medical information shall interpret the reproducibility and peer-review standards in a manner appropriate to assuring the timely flow of vital information from agencies to medical providers, patients, health agencies, and the public. Information quality standards may be waived temporarily by agencies under urgent situations (*e.g.*, imminent threats to public health or homeland security) in accordance with the latitude specified in agency-specific guidelines.

4. "Integrity" refers to the security of information—protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.

5. "Information" means any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes it clear that what is being offered is someone's opinion rather than fact or the agency's views.

6. "Government information" means information created, collected, processed, disseminated, or disposed of by or for the Federal Government.

7. "Information dissemination product" means any books, paper, map, machine-readable material, audiovisual production, or other documentary material, regardless of physical form or characteristic, an agency disseminates to the public. This definition includes any electronic document, CD–ROM, or web page.

8. "Dissemination" means agency initiated or sponsored distribution of information to the public (see 5 CFR 1320.3(d) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas or adjudicative processes.

9. "Influential", when used in the phrase "influential scientific, financial, or statistical information", means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. Each agency is authorized to define "influential" in ways appropriate for it given the nature and multiplicity of issues for which the agency is responsible.

10. "Reproducibility" means that the information is capable of being substantially reproduced, subject to an acceptable degree of imprecision. For information judged to have more (less) important impacts, the degree of imprecision that is tolerated is reduced (increased). If agencies apply the reproducibility test to specific types of original or supporting data, the associated guidelines shall provide relevant definitions of reproducibility (*e.g.*, standards for replication of laboratory data). With respect to analytic results, "capable of being substantially reproduced" means that independent analysis of the original or supporting data using identical methods would generate similar analytic results, subject to an acceptable degree of imprecision or error.

[FR Doc. 02–59 Filed 1–2–02; 1:36 pm]
BILLING CODE 3110–01–M

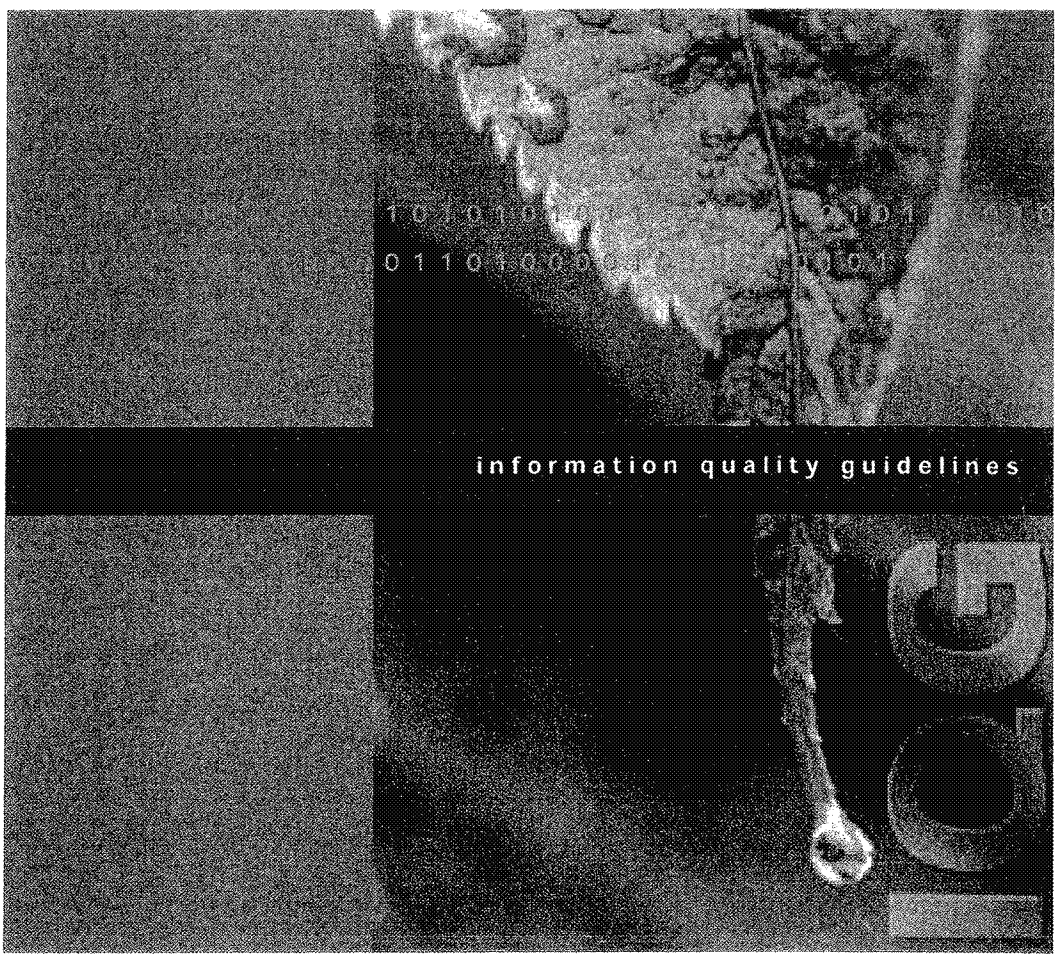
Editorial Note: Due to numerous errors, this document is being reprinted in its entirety. It was originally printed in the **Federal Register** on Thursday, January 3, 2002 at 67 FR 369–378 and was corrected on Tuesday, February 5, 2002 at 67 FR 5365.

[FR Doc. R2–59 Filed 2–21–02; 8:45 am]
BILLING CODE 1505–01–D

APPENDIX C – 2

EXCERPTS

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency



EPA/260R-02-008
October 2002

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency

Prepared by:

U.S. Environmental Protection Agency
Office of Environmental Information (2810)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Addendum
06/24/2004

This addendum updates the contact information for submittal of Requests for Correction under the Information Quality Guidelines (Section 8.2 of the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA*, October, 2002)

An affected person may submit an RFC via any one of the methods listed here:

- **E-mail** at quality@epa.gov
- **Fax** at (202) 565-2441
- **Mail** to Information Quality Guidelines Staff, Mail Code 2811R, U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington, DC, 20460
- **By courier or in person** to Information Quality Guidelines Staff, Ronald Reagan Building, Room M1200, 1300 Pennsylvania Ave., N.W., Washington, DC

Addendum
05/13/2005

This addendum updates the link for the EPA Integrated Error Correction Process found in Section 4.4, footnote 8, page 12 of the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by EPA*, October, 2002.

---

[8] Integrated Error Correction Process for Environmental Data. http://oaspub.epa.gov/enviro/ets_grab_error.smart_form

Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency

Table of Contents

1 Introduction 3

2 EPA Mission and Commitment to Quality 5
- 2.1 EPA's Mission and Commitment to Public Access 5
- 2.2 Information Management in EPA 5
- 2.3 EPA's Relationship with State, Tribal, and Local Governments 8

3 OMB Guidelines 9

4 Existing Policies and Procedures that Ensure and Maximize Information Quality 10
- 4.1 Quality System 10
- 4.2 Peer Review Policy 11
- 4.3 Action Development Process 12
- 4.4 Integrated Error Correction Process 12
- 4.5 Information Resources Management Manual 13
- 4.6 Risk Characterization Policy and Handbook 13
- 4.7 Program-Specific Policies 13
- 4.8 EPA Commitment to Continuous Improvement 14
- 4.9 Summary of New Activities and Initiatives 14

5 Guidelines Scope and Applicability 15
- 5.1 What is "Quality" According to the Guidelines? 15
- 5.2 What is the Purpose of these Guidelines? 15
- 5.3 When Do these Guidelines Apply? 15
- 5.4 What is Not Covered by these Guidelines? 16
- 5.5 What Happens if Information is Initially Not Covered by these Guidelines, but EPA Subsequently Disseminates it to the Public? 18
- 5.6 How does EPA Ensure the Objectivity, Utility, and Integrity of information that is not covered by these Guidelines? 18

6 Guidelines for Ensuring and Maximizing Information Quality 19
- 6.1 How does EPA Ensure and Maximize the Quality of Disseminated Information? 19
- 6.2 How Does EPA Define Influential Information for these Guidelines? 19
- 6.3 How Does EPA Ensure and Maximize the Quality of "Influential" Information? 20
- 6.4 How Does EPA Ensure and Maximize the Quality of "Influential" Scientific Risk Assessment Information? 21
- 6.5 Does EPA Ensure and Maximize the Quality of Information from External Sources? 28

7 Administrative Mechanism for Pre-dissemination Review 29
7.1 What are the Administrative Mechanisms for Pre-dissemination Reviews? 29

8 Administrative Mechanisms for Correction of Information 30
8.1 What are EPA's Administrative Mechanisms for Affected Persons to Seek and Obtain Correction of Information? 30
8.2 What Should be Included in a Request for Correction of Information? 30
8.3 When Does EPA Intend to Consider a Request for Correction of Information? 31
8.4 How Does EPA Intend to Respond to a Request for Correction of Information? 31
8.5 How Does EPA Expect to Process Requests for Correction of Information on Which EPA has Sought Public Comment? 32
8.6 What Should be Included in a Request Asking EPA to Reconsider its Decision on a Request for the Correction of Information? 34
8.7 How Does EPA Intend to Process Requests for Reconsideration of EPA Decisions? 34

Appendix A: IQG Development Process and Discussion of Public Comments 36

A.1 Introduction 36

A.2 General Summary of Comments 37

A.3 Response to Comments by Guidelines Topic Area 38
A.3.1 Existing Policy 38
A.3.2 Scope and Applicability 39
A.3.3 Sources of Information 42
A.3.4 Influential Information 43
A.3.5 Reproducibility 47
A.3.6 Influential Risk Assessment 48
A.3.7 Complaint Resolution 53

A.4 Next Steps 56

1 Introduction

The Environmental Protection Agency (EPA) is committed to providing public access to environmental information. This commitment is integral to our mission to protect human health and the environment. One of our goals is that all parts of society - including communities, individuals, businesses, State and local governments, Tribal governments - have access to accurate information sufficient to effectively participate in managing human health and environmental risks. To fulfill this and other important goals, EPA must rely upon information of appropriate quality for each decision we make.

Developed in response to guidelines issued by the Office of Management and Budget (OMB)[1] under Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658), the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (the Guidelines) contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information we disseminate. The Guidelines also outline administrative mechanisms for EPA pre-dissemination review of information products and describe some new mechanisms to enable affected persons to seek and obtain corrections from EPA regarding disseminated information that they believe does not comply with EPA or OMB guidelines. Beyond policies and procedures these Guidelines also incorporate the following performance goals:

- Disseminated information should adhere to a basic standard of quality, including objectivity, utility, and integrity.
- The principles of information quality should be integrated into each step of EPA's development of information, including creation, collection, maintenance, and dissemination.
- Administrative mechanisms for correction should be flexible, appropriate to the nature and timeliness of the disseminated information, and incorporated into EPA's information resources management and administrative practices.

OMB encourages agencies to incorporate standards and procedures into existing information resources management practices rather than create new, potentially duplicative processes. EPA has taken this advice and relies on numerous existing quality-related policies in these Guidelines. EPA will work to ensure seamless implementation into existing practices. It is expected that EPA managers and staff will familiarize themselves with these Guidelines, and will carefully review existing program policies and procedures in order to accommodate the principles outlined in this document.

---

[1]Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, OMB, 2002. (67 FR 8452) Herein after "OMB guidelines". http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf

EPA's Guidelines are intended to carry out OMB's government-wide policy regarding information we disseminate to the public. Our Guidelines reflect EPA's best effort to present our goals and commitments for ensuring and maximizing the quality of information we disseminate. As such, they are not a regulation and do not change or substitute for any legal requirements. They provide non-binding policy and procedural guidance, and are therefore not intended to create legal rights, impose legally binding requirements or obligations on EPA or the public when applied in particular situations, or change or impact the status of information we disseminate, nor to contravene any other legal requirements that may apply to particular agency determinations or other actions. EPA's intention is to fully implement these Guidelines in order to achieve the purposes of Section 515.

These Guidelines are the product of an open, collaborative process between EPA and numerous EPA stakeholders. The Guidelines development process is described in the Appendix to this document. EPA received many public comments and has addressed most comments in these Guidelines. A discussion of public comments is also provided in the Appendix and is grouped by overarching themes and comments by Guidelines topic areas. EPA views these Guidelines as a living document, and anticipates their revision as we work to further ensure and maximize information quality.

2 EPA Mission and Commitment to Quality

2.1 EPA's Mission and Commitment to Public Access

The mission of the EPA is to protect human health and safeguard the natural environment upon which life depends. EPA is committed to making America's air cleaner, water purer, and land better protected and to work closely with its Federal, State, Tribal, and local government partners; with citizens; and with the regulated community to accomplish its mission. In addition, the United States plays a leadership role in working with other nations to protect the global environment.

EPA's commitment to expanding and enhancing access to environmental information is articulated in our Strategic Plan. EPA works every day to expand the public's right to know about and understand their environment by providing and facilitating access to a wealth of information about public health and local environmental issues and conditions. This enhances citizen understanding and involvement and provides people with tools to protect their families and their communities.

EPA statutory responsibilities to protect human health and safeguard the natural environment are described in the statutes that mandate and govern our programs. EPA manages those programs in concert with numerous other government and private sector partners. As Congress intended, each statute provides regulatory expectations including information quality considerations and principles. Some statutes are more specific than others, but overall, each directs EPA and other agencies in how we regulate to protect human health and the environment. For example, the Safe Drinking Water Act (SDWA) Amendments of 1996 set forth certain quality principles for how EPA should conduct human health risk assessments and characterize the potential risks to humans from drinking water contaminants. Information quality is a key component of every statute that governs our mission.

2.2 Information Management in EPA

The collection, use, and dissemination of information of known and appropriate quality are integral to ensuring that EPA achieves its mission. Information about human health and the environment -- environmental characteristics; physical, chemical, and biological processes; and chemical and other pollutants -- underlies all environmental management and health protection decisions. The availability of, and access to, information and the analytical tools to understand it are essential for assessing environmental and human health risks, designing appropriate and cost-effective policies and response strategies, and measuring environmental improvements.

EPA works every day to ensure information quality, but we do not wait until the point of dissemination to consider important quality principles. While the final review of a document before it is published is very important to ensuring a product of high quality, we know that in order to maximize quality, we must start much earlier. When you read an EPA report at your local library or view EPA information on our web site, that information is the result of processes

undertaken by EPA and our partners that assured quality along each step of the way. To better describe this interrelated information quality process, the following presents some of the major roles that EPA plays in its effort to ensure and maximize the quality of the information:

- **EPA is a collector and generator of information:** While most of our programs rely on States, Tribes, or the private sector to collect and report information to EPA, there are some programs in which EPA collects its own information. One example is the Agency's enforcement and compliance program, under which EPA collects samples in the field or conducts onsite inspections. We also conduct original, scientific research at headquarters, in Regional Offices, and at our research laboratories to investigate and better understand how our environment works, how humans react to chemical pollutants and other environmental contaminants, and how to model our natural environment to assess the potential impact of environmental management activities. Ensuring the quality of collected information is central to our mission.

- **EPA is a recipient of information:** EPA receives a large amount of information that external parties volunteer or provide under statutory and other mandates. Much of the environmental information submitted to EPA is processed and stored in Agency information management systems. While, we work to ensure and maximize the integrity of that information through a variety of mechanisms and policies, we have varying levels of quality controls over information developed or collected by outside parties. This information generally falls into one of four categories:

  - **Information collected through contracts with EPA**. Examples of this information include studies and collection and analysis of data by parties that are under a contractual obligation with EPA. Since EPA is responsible for managing the work assigned to contractors, EPA has a relatively high degree of control over the quality of this information.

  - **Information collected through grants and cooperative agreements with EPA**. Examples of this information include scientific studies that are performed under research grants and data collected by State agencies or other grantees to assess regulatory compliance or environmental trends. Although EPA has less control over grantees than contractors, EPA can and does include conditions in grants and cooperative agreements requiring recipients to meet certain criteria.

  - **Information submitted to EPA as part of a requirement under a statute, regulation, permit, order or other mandate**. Examples of this information include required test data for pesticides or chemicals, Toxics Release Inventory (TRI) submissions and compliance information submitted to EPA by States and the regulated community. EPA ensures

quality control of such information through regulatory requirements, such as requiring samples to be analyzed by specific analytical procedures and by certified laboratories. However, each EPA program has specific statutory authorities which may affect its ability to impose certain quality practices.

- The final category of information that is not included in any of the above three categories includes **information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory, or other decision.** Examples of this information include scientific studies published in journal articles and test data obtained from other Federal agencies, industry, and others. EPA may not have any financial ties or regulatory requirements to control the quality of this type of information.

While the quality of information submitted to EPA is the responsibility of the original collector of the information, we nevertheless maintain a robust quality system, that addresses information related to the first three bullets above by including regulatory requirements for quality assurance for EPA contracts, grants, and assistance agreements. For the fourth category, we intend to develop and publish factors that EPA would use in the future to assess the quality of voluntary submissions or information that the Agency gathers for its own use.

- **EPA is a user of information:** Upon placement in our information management systems, information becomes available for use by many people and systems. EPA users may include Program managers, information product developers, or automated financial tracking systems. Depending on the extent of public release, users may also include city planners, homeowners, teachers, engineers, or community activists, to name a few. To satisfy this broad spectrum of users, it is critical that we present information in an unbiased context with thorough documentation.

  EPA is moving beyond routine administration of regulatory information and working in concert with States and other stakeholders to provide new information products that are responsive to identified users. Increasingly, information products are derived from information originally collected to support State or Federal regulatory programs or management activities. Assuring the suitability of this information for new applications is of paramount importance.

- **EPA is a conduit for information:** Another major role that EPA plays in the management of information is as a provider of public access. Such access enables public involvement in how EPA achieves it mission. We provide access to a variety of information holdings. Some information distributed by EPA includes information collected through contracts; information collected through grants and

cooperative agreements; information submitted to EPA as part of a requirement under a statute, regulation, permit, order, or other mandate; and information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory, or other decision. In some cases, EPA serves as an important conduit for information generated by external parties; however, the quality of that information is the responsibility of the external information developer, unless EPA endorses or adopts it.

2.3 EPA's Relationship with State, Tribal, and Local Governments

As mentioned in the previous section, EPA works with a variety of partners to achieve its mission. Our key government partners not only provide information, they also work with EPA to manage and implement programs and communicate with the public about issues of concern. In addition to implementing national programs through EPA Headquarters Program Offices, a vast network of EPA Regions and other Federal, State, Tribal and local governments implement both mandated and voluntary programs. This same network collects, uses, and distributes a wide range of information. EPA plans to coordinate with these partners to ensure the Guidelines are appropriate and effective.

One major mechanism to ensure and maximize information integrity is the National Environmental Information Exchange Network (NEIEN, or Network). The result of an important partnership between EPA, States and Tribal governments, the Network seeks to enhance the Agency's information architecture to ensure timely and one-stop reporting from many of EPA's information partners. Key components include the establishment of the Central Data Exchange (CDX) portal and a System of Access for internal and external users. When fully implemented, the Network and its many components will enhance EPA and the public's ability to access, use, and integrate information and the ability of external providers to report to EPA.

3 OMB Guidelines

In Section 515(a) of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Public Law 106-554; H.R. 5658), Congress directed OMB to issue government-wide guidelines that "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies...." The OMB guidelines direct agencies subject to the Paperwork Reduction Act (44 U.S.C. 3502(1)) to:

- Issue their own information quality guidelines to ensure and maximize the quality, objectivity, utility, and integrity of information, including statistical information, by no later than one year after the date of issuance of the OMB guidelines;
- Establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply with the OMB or agency guidelines; and
- Report to the Director of OMB the number and nature of complaints received by the agency regarding agency compliance with OMB guidelines concerning the quality, objectivity, utility, and integrity of information and how such complaints were resolved.

The OMB guidelines provide some basic principles for agencies to consider when developing their own guidelines including:

- Guidelines should be flexible enough to address all communication media and variety of scope and importance of information products.
- Some agency information may need to meet higher or more specific expectations for objectivity, utility, and integrity. Information of greater importance should be held to a higher quality standard.
- Ensuring and maximizing quality, objectivity, utility, and integrity comes at a cost, so agencies should use an approach that weighs the costs and benefits of higher information quality.
- Agencies should adopt a common sense approach that builds on existing processes and procedures. It is important that agency guidelines do not impose unnecessary administrative burdens or inhibit agencies from disseminating quality information to the public.

4 Existing Policies and Procedures that Ensure and Maximize Information Quality

EPA is dedicated to the collection, generation, and dissemination of high quality information. We disseminate a wide variety of information products, ranging from comprehensive scientific assessments of potential health risks,[2] to web-based applications that provide compliance information and map the location of regulated entities,[3] to simple fact sheets for school children.[4] As a result of this diversity of information-related products and practices, different EPA programs have evolved specialized approaches to information quality assurance. The OMB guidelines encourage agencies to avoid the creation of "new and potentially duplicative or contradictory processes." Further, OMB stresses that its guidelines are not intended to "impose unnecessary administrative burdens that would inhibit agencies from continuing to take advantage of the Internet and other technologies to disseminate information that can be of great benefit and value to the public." In this spirit, EPA seeks to foster the continuous improvement of existing information quality activities and programs. In implementing these guidelines, we note that ensuring the quality of information is a key objective alongside other EPA objectives, such as ensuring the success of Agency missions, observing budget and resource priorities and restraints, and providing useful information to the public. EPA intends to implement these Guidelines in a way that will achieve all these objectives in a harmonious way in conjunction with our existing guidelines and policies, some of which are outlined below. These examples illustrate some of the numerous systems and practices in place that address the quality, objectivity, utility, and integrity of information.

4.1 Quality System

The EPA Agency-wide Quality System helps ensure that EPA organizations maximize the quality of environmental information, including information disseminated by the Agency. A graded approach is used to establish quality criteria that are appropriate for the intended use of the information and the resources available. The Quality System is documented in EPA Order 5360.1 A2, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" and the "EPA Quality Manual."[5] To implement the Quality System, EPA organizations (1) assign a quality assurance manager, or person assigned to an equivalent position, who has sufficient technical and management expertise and authority to conduct independent oversight of the implementation of the organization's quality system; (2) develop a Quality Management Plan, which documents the organization's quality system; (3) conduct an annual assessment of the organization's quality system; (4) use a systematic planning process to develop acceptance or performance criteria prior to the initiation of all projects that involve environmental information

[2] http://cfpub.epa.gov/ncea/cfm/partmatt.cfm

[3] http://www.epa.gov/enviro/wme/

[4] http://www.epa.gov/kids

[5] EPA Quality Manual for Environmental Programs 5360 A1. May 2000. http://www.epa.gov/quality/qs-docs/5360.pdf

collection and/or use; (5) develop Quality Assurance Project Plan(s), or equivalent document(s) for all applicable projects and tasks involving environmental data; (6) conduct an assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use; (7) implement all Agency-wide Quality System components in all applicable EPA-funded extramural agreements; and (8) provide appropriate training, for all levels of management and staff.

The EPA Quality System may also apply to non-EPA organizations, with key principles incorporated in the applicable regulations governing contracts, grants, and cooperative agreements. EPA Quality System provisions may also be invoked as part of negotiated agreements such as memoranda of understanding. Non-EPA organizations that may be subject to EPA Quality System requirements include (a) any organization or individual under direct contract to EPA to furnish services or items or perform work (i.e., a contractor) under the authority of 48 CFR part 46, (including applicable work assignments, delivery orders, and task orders); and (b) other government agencies receiving assistance from EPA through interagency agreements. Separate quality assurance requirements for assistance recipients are set forth in 40 CFR part 30 (governing assistance agreements with institutions of higher education, hospitals, and other non-profit recipients of financial assistance) and 40 CFR parts 31 and 35 (government assistance agreements with State, Tribal, and local governments).

4.2 Peer Review Policy

In addition to the Quality System, EPA's Peer Review Policy provides that major scientifically and technically based work products (including scientific, engineering, economic, or statistical documents) related to Agency decisions should be peer-reviewed. Agency managers within Headquarters, Regions, laboratories, and field offices determine and are accountable for the decision whether to employ peer review in particular instances and, if so, its character, scope, and timing. These decisions are made consistent with program goals and priorities, resource constraints, and statutory or court-ordered deadlines. For those work products that are intended to support the most important decisions or that have special importance in their own right, external peer review is the procedure of choice. For other work products, internal peer review is an acceptable alternative to external peer review. Peer review is not restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial. The basis for EPA peer review policy is articulated in *Peer Review and Peer Involvement at the U.S. Environmental Protection Agency*.[6] The Peer Review Policy was first issued in January, 1993, and was updated in June, 1994. In addition to the policy, EPA has published a Peer Review Handbook,[7] which provides detailed guidance for implementing the policy. The handbook was last revised December, 2000.

---

[6]Peer Review and Peer Involvement at the U.S. EPA. June 7, 1994. http://www.epa.gov/osp/spc/perevmem.htm

[7]Peer Review Handbook, 2nd Edition, U.S. EPA, Science Policy Council, December 2000, EPA 100-B-00-001. http://www.epa.gov/osp/spc/prhandbk.pdf

4.3 Action Development Process

The Agency's Action Development Process also serves to ensure and maximize the quality of EPA disseminated information. Top Agency actions and Economically Significant actions as designated under Executive Order 12866 are developed as part of the Agency's Action Development Process. The Action Development Process ensures the early and timely involvement of senior management at key decision milestones to facilitate the consideration of a broad range of regulatory and non-regulatory options and analytic approaches. Of particular importance to the Action Development Process is ensuring that our scientists, economists, and others with technical expertise are appropriately involved in determining needed analyses and research, identifying alternatives, and selecting options. Program Offices and Regional Offices are invited to participate to provide their unique perspectives and expertise. Effective consultation with policy advisors (e.g., Senior Policy Council, Science Policy Council), co-regulators (e.g., States, Tribes, and local governments), and stakeholders is also part of the process. Final Agency Review (FAR) generally takes place before the release of substantive information associated with these actions. The FAR process ensures the consistency of any policy determinations, as well as the quality of the information underlying each policy determination and its presentation.

4.4 Integrated Error Correction Process

The Agency's Integrated Error Correction Process[8] (IECP) is a process by which members of the public can notify EPA of a potential data error in information EPA distributes or disseminates. This process builds on existing data processes through which discrete, numerical errors in our data systems are reported to EPA. The IECP has made these tools more prominent and easier to use. Individuals who identify potential data errors on the EPA web site can contact us through the IECP by using the "Report Error" button or error correction hypertext found on major data bases throughout EPA's web site. EPA reviews the error notification and assists in bringing the notification to resolution with those who are responsible for the data within or outside the Agency, as appropriate. The IECP tracks this entire process from notification through final resolution.

[8]Integrated Error Correction Process for Environmental Data. http://www.epa.gov/cdx/iecp.html

4.5 Information Resources Management Manual

The EPA Information Resources Management (IRM) Manual[9] articulates and describes many of our information development and management procedures and policies, including information security, data standards, records management, information collection, and library services. Especially important in the context of the Guidelines provided in this document, the IRM Manual describes how we maintain and ensure information integrity. We believe that maintaining information integrity refers to keeping information "unaltered," i.e., free from unauthorized or accidental modification or destruction. These integrity principles apply to all information. Inappropriately changed or modified data or software impacts information integrity and compromises the value of the information system. Because of the importance of EPA's information to the decisions made by the Agency, its partners, and the public, it is our responsibility to ensure that the information is, and remains, accurate and credible.

Beyond addressing integrity concerns, the IRM Manual also includes Agency policy on public access and records management. These are key chapters that enable EPA to ensure transparency and the reproducibility of information.

4.6 Risk Characterization Policy and Handbook

The EPA Risk Characterization Policy and Handbook[10] provide guidance for risk characterization that is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk. The Policy calls for a transparent process and products that are clear, consistent and reasonable. The Handbook is designed to provide risk assessors, risk managers, and other decision-makers an understanding of the goals and principles of risk characterization.

4.7 Program-Specific Policies

We mentioned just a few of the Agency's major policies that ensure and maximize the quality of information we disseminate. In addition to these Agency-wide systems and procedures, Program Offices and Regions implement many Office-level and program-specific procedures to ensure and maximize information quality. The purpose of these Guidelines is to serve as a common thread that ties all these policies together under the topics provided by OMB: objectivity, integrity and utility. EPA's approach to ensuring and maximizing quality is necessarily distributed across all levels of EPA's organizational hierarchy, including Offices, Regions, divisions, projects, and even products. Oftentimes, there are different quality considerations for different types of products. For example, the quality principles associated with a risk assessment

---

[9] EPA Directive 2100 Information Resources Management Policy Manual. http://www.epa.gov/irmpoli8/polman/

[10] Risk Characterization Handbook, U.S. EPA, Science Policy Council, December 2000. http://www.epa.gov/osp/spc/2riskchr.htm

differ from those associated with developing a new model. The Agency currently has a comprehensive but distributed system of policies to address such unique quality considerations. These Guidelines provide us with a mechanism to help coordinate and synthesize our quality policies and procedures.

4.8 EPA Commitment to Continuous Improvement

As suggested above, we will continue to work to ensure that our many policies and procedures are appropriately implemented, synthesized, and revised as needed. One way to build on achievements and learn from mistakes is to document lessons learned about specific activities or products. For example, the documents that present guidance and tools for implementing the Quality System are routinely subjected to external peer review during their development; comments from the reviewers are addressed and responses reviewed by management before the document is issued. Each document is formally reviewed every five years and is either reissued, revised as needed, or rescinded. If important new information or approaches evolve between reviews, the document may be reviewed and revised more frequently.

4.9 Summary of New Activities and Initiatives

In response to OMB's guidelines, EPA recognizes that it will be incorporating new policies and administrative mechanisms. As we reaffirm our commitment to our existing policies and procedures that ensure and maximize quality, we also plan to address the following new areas of focus and commitment:

- Working with the public to develop assessment factors that we will use to assess the quality of information developed by external parties, prior to EPA's use of that information.

- Affirming a new commitment to information quality, especially the transparency of information products.

- Establishing Agency-wide correction process and request for reconsideration panel to provide a centralized point of access for all affected parties to seek and obtain the correction of disseminated information that they believe does not conform to these Guidelines or the OMB guidelines.

5 Guidelines Scope and Applicability

5.1 What is "Quality" According to the Guidelines?

Consistent with the OMB guidelines, EPA is issuing these Guidelines to ensure and maximize the quality, including objectivity, utility and integrity, of disseminated information. Objectivity, integrity, and utility are defined here, consistent with the OMB guidelines. "Objectivity" focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased. "Integrity" refers to security, such as the protection of information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification. "Utility" refers to the usefulness of the information to the intended users.

5.2 What is the Purpose of these Guidelines?

The collection, use, and dissemination of information of known and appropriate quality is integral to ensuring that EPA achieves its mission. Information about the environment and human health underlies all environmental management decisions. Information and the analytical tools to understand it are essential for assessing environmental and human health risks, designing appropriate and cost-effective policies and response strategies, and measuring environmental improvements.

These Guidelines describe EPA's policy and procedures for reviewing and substantiating the quality of information before EPA disseminates it. They describe our administrative mechanisms for enabling affected persons to seek and obtain, where appropriate, correction of information disseminated by EPA that they believe does not comply with EPA or OMB guidelines.

5.3 When Do these Guidelines Apply?

These Guidelines apply to "information" EPA disseminates to the public. "Information," for purposes of these Guidelines, generally includes any communication or representation of knowledge such as facts or data, in any medium or form. Preliminary information EPA disseminates to the public is also considered "information" for the purposes of the Guidelines. Information generally includes material that EPA disseminates from a web page. However not all web content is considered "information" under these Guidelines (e.g., certain information from outside sources that is not adopted, endorsed, or used by EPA to support an Agency decision or position).

For purposes of these Guidelines, EPA disseminates information to the public when EPA initiates or sponsors the distribution of information to the public.

- EPA initiates a distribution of information if EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.

- EPA initiates a distribution of information if EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it; if EPA indicates in its distribution that the information supports or represents EPA's viewpoint; or if EPA in its distribution proposes to use or uses the information to formulate or support a regulation, guidance, policy, or other Agency decision or position.

- Agency-sponsored distribution includes instances where EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

EPA intends to use notices to explain the status of information, so that users will be aware of whether the information is being distributed to support or represent EPA's viewpoint.

5.4 What is Not Covered by these Guidelines?

If an item is not considered "information," these Guidelines do not apply. Examples of items that are not considered information include Internet hyperlinks and other references to information distributed by others, and opinions, where EPA's presentation makes it clear that what is being offered is someone's opinion rather than fact or EPA's views.

"Dissemination" for the purposes of these Guidelines does not include distributions of information that EPA does not initiate or sponsor. Below is a sample of various types of information that would not generally be considered disseminated by EPA to the public:

- Distribution of information intended only for government employees (including intra- or interagency use or sharing) or recipients of government contracts, grants, or cooperative agreements. Intra-agency use of information includes use of information pertaining to basic agency operations, such as management, personnel, and organizational information.

- EPA's response to requests for agency records under the Freedom of Information Act (FOIA), the Privacy Act, the Federal Advisory Committee Act (FACA), or other similar laws.

- Distribution of information in correspondence directed to individuals or persons (i.e., any individual, group, or entity, including any government or political subdivision thereof, or Federal governmental component/unit).

- Information of an ephemeral nature, such as press releases, fact sheets, press conferences, and similar communications, in any medium that advises the public of an event or activity or announces information EPA has disseminated

elsewhere; interviews, speeches, and similar communications that EPA does not disseminate to the public beyond their original context, such as by placing them on the Internet. If a speech, press release, or other "ephemeral" communication is about an information product disseminated elsewhere by EPA, the product itself will be covered by these Guidelines.

- Information presented to Congress as part of the legislative or oversight processes, such as testimony of officials, information, or drafting assistance provided to Congress in connection with pending or proposed legislation, unless EPA simultaneously disseminates this information to the public.

- Background information such as published articles distributed by libraries or by other distribution methods that do not imply that EPA has adopted or endorsed the materials. This includes outdated or superseded EPA information that is provided as background information but no longer reflects EPA policy or influences EPA decisions, where the outdated or superseded nature of such material is reasonably apparent from its form of presentation or date of issuance, or where EPA indicates that the materials are provided as background materials and do not represent EPA's current view.

- These Guidelines do not apply to information distributed by recipients of EPA contracts, grants, or cooperative agreements, unless the information is disseminated on EPA's behalf, as when EPA specifically directs or approves the dissemination. These Guidelines do not apply to the distribution of any type of research by Federal employees and recipients of EPA funds, where the researcher (not EPA) decides whether and how to communicate and publish the research, does so in the same manner as his or her academic colleagues, and distributes the research in a manner that indicates it does not necessarily represent EPA's official position (for example, by including an appropriate disclaimer). The Guidelines do not apply even if EPA retains ownership or other intellectual property rights because the Federal government paid for the research.

- Distribution of information in public filings to EPA, including information submitted to EPA by any individual or person (as discussed above), either voluntarily or under mandates or requirements (such as filings required by statutes, regulations, orders, permits, or licenses). The Guidelines do not apply where EPA distributes this information simply to provide the public with quicker and easier access to materials submitted to EPA that are publicly available. This will generally be the case so long as EPA is not the author, and is not endorsing, adopting, using, or proposing to use the information to support an Agency decision or position.

- Distribution of information in documents filed in or prepared specifically for a judicial case or an administrative adjudication and intended to be limited to such

actions, including information developed during the conduct of any criminal or civil action or administrative enforcement action, investigation, or audit involving an agency against specific parties.

5.5 What Happens if Information is Initially Not Covered by these Guidelines, but EPA Subsequently Disseminates it to the Public?

If a particular distribution of information is not covered by these Guidelines, the Guidelines may still apply to a subsequent dissemination of the information in which EPA adopts, endorses, or uses the information to formulate or support a regulation, guidance, or other Agency decision or position. For example, if EPA simply makes a public filing (such as facility data required by regulation) available to the public, these Guidelines would not apply to that distribution of information. However, if EPA later includes the information in a background document in support of a rulemaking, these Guidelines would apply to that later dissemination of the information in that document.

5.6 How does EPA Ensure the Objectivity, Utility, and Integrity of information that is not covered by these Guidelines?

These Guidelines apply only to information EPA disseminates to the public, outlined in section 5.3, above. Other information distributed by EPA that is not covered by these Guidelines is still subject to all applicable EPA policies, quality review processes, and correction procedures. These include quality management plans for programs that collect, manage, and use environmental information, peer review, and other procedures that are specific to individual programs and, therefore, not described in these Guidelines. It is EPA's policy that all of the information it distributes meets a basic standard of information quality, and that its utility, objectivity, and integrity be scaled and appropriate to the nature and timeliness of the planned and anticipated uses. Ensuring the quality of EPA information is not necessarily dependent on any plans to disseminate the information. EPA continues to produce, collect, and use information that is of the appropriate quality, irrespective of these Guidelines or the prospects for dissemination of the information.

6 Guidelines for Ensuring and Maximizing Information Quality

6.1 How does EPA Ensure and Maximize the Quality of Disseminated Information?

EPA ensures and maximizes the quality of the information we disseminate by implementing well established policies and procedures within the Agency as appropriate to the information product. There are many tools that the Agency uses such as the Quality System,[11] review by senior management, peer review process,[12] communications product review process,[13] the web guide,[14] and the error correction process.[15] Beyond our internal quality management system, EPA also ensures the quality of information we disseminate by seeking input from experts and the general public. EPA consults with groups such as the Science Advisory Board and the Science Advisory Panel, in addition to seeking public input through public comment periods and by hosting public meetings.

For the purposes of the Guidelines, EPA recognizes that if data and analytic results are subjected to formal, independent, external peer review, the information may generally be presumed to be of acceptable objectivity. However, this presumption of objectivity is rebuttable. The Agency uses a graded approach and uses these tools to establish the appropriate quality, objectivity, utility, and integrity of information products based on the intended use of the information and the resources available. As part of this graded approach, EPA recognizes that some of the information it disseminates includes influential scientific, financial, or statistical information, and that this category should meet a higher standard of quality.

6.2 How Does EPA Define Influential Information for these Guidelines?

"Influential," when used in the phrase "influential scientific, financial, or statistical information," means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact (i.e., potential change or effect) on important public policies or private sector decisions.[16] For the purposes of the EPA's

---

[11]EPA Quality Manual for Environmental Programs 5360 A1. May 2000. http://www.epa.gov/quality/qs-docs/5360.pdf

[12]Peer Review Handbook, 2nd Edition, U.S. EPA, Science Policy Council, December 2000, EPA 100-B-00-001. http://www.epa.gov/osp/spc/prhandbk.pdf

[13]EPA's Print and Web Communications Product Review Guide. http://www.epa.gov/dced/pdf/review.pdf

[14]Web Guide. U.S. EPA. http://www.epa.gov/webguide/resources/webserv.html

[15]Integrated Error Correction Process. http://www.epa.gov/cdx/iecp.html

[16]The term "clear and substantial impact" is used as part of a definition to distinguish different categories of information for purposes of these Guidelines. EPA does not intend the classification of information under this definition to change or impact the status of the information in any other setting, such as for purposes of determining whether the dissemination of the information is a final Agency action.

Information Quality Guidelines, EPA will generally consider the following classes of information to be influential, and, to the extent that they contain scientific, financial, or statistical information, that information should adhere to a rigorous standard of quality:

- Information disseminated in support of top Agency actions (i.e., rules, substantive notices, policy documents, studies, guidance) that demand the ongoing involvement of the Administrator's Office and extensive cross-Agency involvement; issues that have the potential to result in major cross-Agency or cross-media policies, are highly controversial, or provide a significant opportunity to advance the Administrator's priorities. Top Agency actions usually have potentially great or widespread impacts on the private sector, the public or state, local or tribal governments. This category may also include precedent-setting or controversial scientific or economic issues.

- Information disseminated in support of Economically Significant actions as defined in Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), Agency actions that are likely to have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, Tribal, or local governments or communities.

- Major work products undergoing peer review as called for under the Agency's Peer Review Policy. Described in the *Science Policy Council Peer Review Handbook,* the EPA Peer Review Policy regards major scientific and technical work products as those that have a major impact, involve precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review. These Major work products are typically subjected to external peer review. Some products that may not be considered "major" under the EPA Peer Review Policy may be subjected to external peer review but EPA does not consider such products influential for purposes of these Guidelines.

- Case-by-case: The Agency may make determinations of what constitutes "influential information" beyond those classes of information already identified on a case-by-case basis for other types of disseminated information that may have a clear and substantial impact on important public policies or private sector decisions.

6.3 How Does EPA Ensure and Maximize the Quality of "Influential" Information?

EPA recognizes that influential scientific, financial, or statistical information should be subject to a higher degree of quality (for example, transparency about data and methods) than information that may not have a clear and substantial impact on important public policies or private sector decisions. A higher degree of transparency about data and methods will facilitate

the reproducibility of such information by qualified third parties, to an acceptable degree of imprecision. For disseminated influential original and supporting data, EPA intends to ensure reproducibility according to commonly accepted scientific, financial, or statistical standards. It is important that analytic results for influential information have a higher degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed. It is also important that the degree of rigor with which each of these factors is presented and discussed be scaled as appropriate, and that all factors be presented and discussed. In addition, if access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should, to the extent practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken. Original and supporting data may not be subject to the high and specific degree of transparency provided for analytic results; however, EPA should apply, to the extent practicable, relevant Agency policies and procedures to achieve reproducibility, given ethical, feasibility, and confidentiality constraints.

Several Agency-wide and Program- and Region-specific policies and processes that EPA uses to ensure and maximize the quality of environmental data, including disseminated information products, would also apply to information considered "influential" under these Guidelines. Agency-wide processes of particular importance to ensure the quality, objectivity, and transparency of "influential" information include the Agency's Quality System, Action Development Process, Peer Review Policy, and related procedures. Many "influential" information products may be subject to more than one of these processes.

6.4 How Does EPA Ensure and Maximize the Quality of "Influential" Scientific Risk Assessment Information?

EPA conducts and disseminates a variety of risk assessments. When evaluating environmental problems or establishing standards, EPA must comply with statutory requirements and mandates set by Congress based on media (air, water, solid, and hazardous waste) or other environmental interests (pesticides and chemicals). Consistent with EPA's current practices, application of these principles involves a "weight-of-evidence" approach that considers all relevant information and its quality, consistent with the level of effort and complexity of detail appropriate to a particular risk assessment. In our dissemination of influential scientific information regarding human health, safety[17] or environmental[18] risk assessments, EPA will ensure, to the extent practicable

[17]"Safety risk assessment" describes a variety of analyses, investigations, or case studies conducted by EPA to respond to environmental emergencies. For example, we work to ensure that the chemical industry and state and local entities take action to prevent, plan and prepare for, and respond to chemical emergencies through the development and sharing of information, tools, and guidance for hazards analyses and risk assessment.

[18]Because the assessment of "environmental risk" is being distinguished from "human health risk," the term "environmental risk" as used in these Guidelines does not directly involve human health concerns. In other words, an "environmental risk assessment" is in this case the equivalent to what EPA commonly calls an "ecological risk

and consistent with Agency statutes and existing legislative regulations, the objectivity[19] of such information disseminated by the Agency by applying the following adaptation of the quality principles found in the Safe Drinking Water Act[20] (SDWA) Amendments of 1996[21]:

(A) The substance of the information is accurate, reliable and unbiased. This involves the use of:

(i) the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies; and

(ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).

(B) The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. In a document made available to the public, EPA specifies:

(i) each population addressed by any estimate of applicable human health risk or each risk assessment endpoint, including populations if applicable, addressed by any estimate of applicable ecological risk[22];

(ii) the expected risk or central estimate of human health risk for the specific

---

assessment".

[19]OMB stated in its guidelines that in disseminating information agencies shall develop a process for reviewing the quality of the information. "Quality" includes objectivity, utility, and integrity. "Objectivity" involves two distinct elements, presentation and substance. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, OMB, 2002. (67 FR 8452) http://www.whitehouse.gov/omb/fedreg/reproducible2.pdf

[20]Safe Drinking Water Act Amendments of 1996, 42 U.S.C. 300g-1(b)(3)(A) & (B)

[21]The exception is risk assessments conducted under SDWA which will adhere to the SDWA principles as amended in 1996.

[22]Agency assessments of human health risks necessarily focus on populations. Agency assessments of ecological risks address a variety of entities, some of which can be described as populations and others (such as ecosystems) which cannot. The phrase "assessment endpoint" is intended to reflect the broader range of interests inherent in ecological risk assessments. As discussed in the *EPA Guidelines for Ecological Risk Assessment* (found at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460), assessment endpoints are explicit expressions of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes. Furthermore, those Guidelines explain that an ecological entity can be a species (e.g., eelgrass, piping plover), a community (e.g., benthic invertebrates), an ecosystem (e.g., wetland), or other entity of concern. An attribute of an assessment endpoint is the characteristic about the entity of concern that is important to protect and potentially at risk. Examples of attributes include abundance (of a population), species richness (of a community), or function (of an ecosystem). Assessment endpoints and ecological risk assessments are discussed more fully in those Guidelines as well as other EPA sources such as *Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments - Interim Final* found at http://www.epa.gov/oerrpage/superfund/programs/risk/ecorisk/ecorisk.htm

populations affected or the ecological assessment endpoints[23], including populations if applicable;

(iii) each appropriate upper-bound or lower-bound estimate of risk;

(iv) each significant uncertainty identified in the process of the assessment of risk and studies that would assist in resolving the uncertainty; and

(v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data.

In applying these principles, "best available" usually refers to the availability at the time an assessment is made. However, EPA also recognizes that scientific knowledge about risk is rapidly changing and that risk information may need to be updated over time. When deciding which influential risk assessment should be updated and when to update it, the Agency will take into account its statutes and the extent to which the updated risk assessment will have a clear and substantial impact on important public policies or private sector decisions. In some situations, the Agency may need to weigh the resources needed and the potential delay associated with incorporating additional information in comparison to the value of the new information in terms of its potential to improve the substance and presentation of the assessment.

Adaptation clarifications

In order to provide more clarity on how EPA adapted the SDWA principles in this guidance in light of our numerous statutes, regulations, guidance and policies that address how to conduct a risk assessment and characterize risk we discuss four adaptations EPA has made to the SDWA quality principles language.

EPA adapted the SDWA principles by adding the phrase "consistent with Agency statutes and existing legislative regulations, the objectivity of such information disseminated by the Agency" in the introductory paragraph, therefore applying to both paragraphs (A) and (B). This was done to explain EPA's intent regarding these quality principles and their implementation consistent with our statutes and existing legislative regulations. Also, as noted earlier, EPA intends to implement these quality principles in conjunction with our guidelines and policies. The procedures set forth in other EPA guidelines set out in more detail EPA's policies for conducting risk assessments, including Agency-wide guidance on various types of risk assessments and program-specific guidance. EPA recognizes that the wide array of programs within EPA have resulted not only in Agency-wide guidance, but in specific protocols that reflect the requirements, including limitations, that are mandated by the various statutes administered by the Agency. For example, the Agency developed several pesticide science policy papers that explained to the public in detail how EPA would implement specific statutory requirements in the Food Quality Protection Act (FQPA) that addressed how we perform risk assessments. We also recognize that emerging issues such endocrine disruption, bioengineered organisms, and genomics may involve some modifications to the existing paradigm for assessing human health

[23]Ibid.

and ecological risks. This does not mean a radical departure from existing guidance or the SDWA principles, but rather indicates that flexibility may be warranted as new information and approaches develop.

EPA introduced the following two adaptations in order to accommodate the range of real-world situations that we confront in the implementation of our diverse programs. EPA adapted the SDWA quality principles by moving the phrase "to the extent practicable" from paragraph (B) to the introductory paragraph in this Guidelines section to cover both parts (A) and (B) of the SDWA adaptation.[24] The phrase refers to situations under (A) where EPA may be called upon to conduct "influential" scientific risk assessments based on limited information or in novel situations, and under (B) in recognition that all such "presentation" information may not be available in every instance. The level of effort and complexity of a risk assessment should also balance the information needs for decision making with the effort needed to develop such information. For example, under the Federal Insecticide, Fungicide and Rodenticide Act[25] (FIFRA) and the Toxic Substances and Control Act[26] (TSCA), regulated entities are obligated to provide information to EPA concerning incidents/test data that may reveal a problem with a pesticide or chemical. We also receive such information voluntarily from other sources. EPA carefully reviews incident reports and factors them as appropriate into risk assessments and decision-making, even though these may not be considered information collected by acceptable methods or best available method as stated in A(ii). Incident information played an important role in the Agency's conclusion that use of chlordane/heptachlor termiticides could result in exposures to persons living in treated homes, and that the registrations needed to be modified accordingly. Similarly, incident reports concerning birdkills and fishkills were important components of the risk assessments for the reregistration of the pesticides phorate and terbufos, respectively. In addition, this adaptation recognizes that while many of the studies incorporated into risk assessments have been peer reviewed, data from other sources may not be peer reviewed. EPA takes many actions based on studies and supporting data provided by outside sources, including confidential or proprietary information that has not been peer reviewed. For example, industry can be required by regulation to submit data for pesticides under FIFRA or for chemicals under TSCA. The data are developed using test guidelines and Good Laboratory Practices (GLPs) in accordance with EPA regulations. While there is not a requirement to have studies peer reviewed, such studies are reviewed by Agency scientists to ensure that they were conducted according to the appropriate test guidelines and GLPs and that the data are valid.

The flexibility provided by applying "to the extent practicable" to paragraph (A) is appropriate in many circumstances to conserve Agency resources and those of the regulated community who otherwise might have to generate significant additional data. This flexibility is already provided

---

[24]The discussion in this and following paragraphs gives some examples of the types of assessments that may under some circumstances be considered influential. These examples are representative of assessments performed under other EPA programs, such as CERCLA

[25]7 U.S.C. 136 et seq.

[26]15 U.S.C. 2601 et seq.

for paragraph (B) in the SDWA quality principles. Pesticide and chemical risk assessments are frequently performed iteratively, with the first iteration employing protective (conservative) assumptions to identify possible risks. Only if potential risks are identified in a screening level assessment, is it necessary to pursue a more refined, data-intensive risk assessment. This is exhibited, for example, in guidance developed for use in CERCLA and RCRA on tiered approaches. In other cases, reliance on "structure activity relationship" or "bridging data" allows the Agency to rely on data from similar chemicals rather than require the generation of new, chemical-specific data. While such assessments may or may not be considered influential under the Guidelines, this adaptation of the SDWA principles reflects EPA's reliance on less-refined risk assessments where further refinement could significantly increase the cost of the risk assessment without significantly enhancing the assessment or changing the regulatory outcome.

In emergency and other time critical circumstances, risk assessments may have to rely on information at hand or that can be made readily available rather than data such as described in (A). One such scenario is risk assessments addressing Emergency Exemption requests submitted under Section 18 of FIFRA[27] which, because of the emergency nature of the request, must be completed within a short time frame. As an example, EPA granted an emergency exemption under Section 18 to allow use of an unregistered pesticide to decontaminate anthrax in a Senate office building. The scientific review and risk assessment to support this action were necessarily constrained by the urgency of the action. Other time-sensitive actions include the reviews of new chemicals under TSCA. Under Section 5 of TSCA[28], EPA must review a large number of pre-manufacture notifications (more than 1,000) every year, not all of which necessarily include "influential" risk assessments, and each review must be completed within a short time frame (generally 90 days). The nature of the reviews and risk assessment associated with these pre-manufacture notifications are affected by the limited time available and the large volume of notifications submitted.

The flexibility provided by applying "to the extent practicable" to paragraph (A) is appropriate to account for safety risk assessment practices. This flexibility is already provided for paragraph (B) in the SDWA quality principles. We applied the same SDWA adaptation for use with human health risk assessments to safety risk assessments with the needed flexibility to apply the principles to the extent practicable. "Safety risk assessments" include a variety of analyses, investigations, or case studies conducted by EPA concerning safety issues. EPA works to ensure that the chemical industry and state and local entities take action to prevent, plan and prepare for, and respond to environmental emergencies and site specific response actions through the development and sharing of information, tools and guidance for hazard analyses and risk assessment. For example, although the chemical industry shoulders most of the responsibility for safety risk assessment and management, EPA may also conduct chemical hazard analyses, investigate the root causes and mechanisms associated with accidental chemical releases, and assess the probability and consequences of accidental releases in support of agency risk

[27] Section 18 of FIFRA, 7 U.S.C. 136p

[28] Section 5 of TSCA, 15 U.S.C. 2604

assessments. Although safety risk assessments can be different from traditional human health risk assessments because they may combine a variety of available information and may use expert judgement based on that information, these assessments provide useful information that is sufficient for the intended purpose.

Next, EPA adapted the SDWA quality principles by adding the clause "including, when available, peer reviewed science and supporting studies" to paragraph (A)(i). It now reads: "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies." In the Agency's development of "influential" scientific risk assessments, we intend to use all relevant information, including peer reviewed studies, studies that have not been peer reviewed, and incident information; evaluate that information based on sound scientific practices as described in our risk assessment guidelines and policies; and reach a position based on careful consideration of all such information (*i.e.*, a process typically referred to as the "weight-of-evidence" approach[29]). In this approach, a well-developed, peer-reviewed study would generally be accorded greater weight than information from a less well-developed study that had not been peer-reviewed, but both studies would be considered. Thus the Agency uses a "weight-of-evidence" process when evaluating peer-reviewed studies along with all other information.

Oftentimes under various EPA-managed programs, EPA receives information that has not been peer-reviewed and we have to make decisions based on the information available. While many of the studies incorporated in risk assessments have been peer reviewed, data from other sources, such as studies submitted to the Agency for pesticides under FIFRA[30] and for chemicals under TSCA, may not always be peer reviewed. Rather, such data, developed under approved guidelines and the application of Good Laboratory Practices (GLPs), are routinely used in the development of risk assessments. Risk assessments may also include more limited data sets such as monitoring data used to support the exposure element of a risk assessment. In cases where these data may not themselves have been peer reviewed their quality and appropriate use would be addressed as part of the peer review of the overall risk assessment as called for under the Agency's peer review guidelines.

Lastly, EPA adapted the SDWA principles for influential environmental ("ecological") risk assessments that are disseminated in order to use terms that are most suited for such risk assessments. Specifically, EPA assessments of ecological risks address a variety of entities,

---

[29] The weight-of-evidence approach generally considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated of each type of evidence, and explains how the various types of evidence fit together. See, e.g., EPA's *Proposed Guidelines for Carcinogen Risk Assessment* (Federal Register 61(79): 17960-18011; April 23, 1996) and EPA's *Guidelines for Carcinogen Risk Assessment* (Federal Register 51(185): 33992-34003; September 24, 1986), available from: www.epa.gov/ncea/raf/, and EPA's Risk Characterization Handbook (*Science Policy Council Handbook: Risk Characterization*, EPA 100-B-00-002, Washington, DC: U.S. EPA, December 2000).

[30] 40 CFR part 158

some of which can be described as populations and others (such as ecosystems) which cannot. Therefore, a specific modification was made to include "assessment endpoints, including populations if applicable" in place of the term "population" for ecological risk assessments and EPA added a footnote directing the reader to various EPA risk policies for further discussion of these concepts in greater detail.

6.5 Does EPA Ensure and Maximize the Quality of Information from External Sources?

Ensuring and maximizing the quality of information from States, other governments, and third parties is a complex undertaking, involving thoughtful collaboration with States, Tribes, the scientific and technical community, and other external information providers. EPA will continue to take steps to ensure that the quality and transparency of information provided by external sources are sufficient for the intended use. For instance, since 1998, the use of environmental data collected by others or for other purposes, including literature, industry surveys, compilations from computerized data bases and information systems, and results from computerized or mathematical models of environmental processes and conditions has been within the scope of the Agency's Quality System[31].

For information that is either voluntarily submitted to EPA in hopes of influencing a decision or that EPA obtains for use in developing a policy, regulatory, or other decision, EPA will continue to work with States and other governments, the scientific and technical community, and other interested information providers to develop and publish factors that EPA would use to assess the quality of this type of information.

For all proposed collections of information that will be disseminated to the public, EPA intends to demonstrate in our Paperwork Reduction Act[32] clearance submissions that the proposed collection of information will result in information that will be collected, maintained and used in ways consistent with the OMB guidelines and these EPA Guidelines. These Guidelines apply to all information EPA disseminates to the public; accordingly, if EPA later identifies a new use for the information that was collected, such use would not be precluded and the Guidelines would apply to the dissemination of the information to the public.

[31] EPA Quality Manual for Environmental Programs 5360 A1. May 2000, Section 1.3.1. http://www.epa.gov/quality/qs-docs/5360.pdf

[32] 44 U.S.C. 3501 et seq.

7 Administrative Mechanism for Pre-dissemination Review

7.1 What are the Administrative Mechanisms for Pre-dissemination Reviews?

Each EPA Program Office and Region will incorporate the information quality principles outlined in section 6 of these Guidelines into their existing pre-dissemination review procedures as appropriate. Offices and Regions may develop unique and new procedures, as needed, to provide additional assurance that the information disseminated by or on behalf of their organizations is consistent with these Guidelines. EPA intends to facilitate implementation of consistent cross-Agency pre-dissemination reviews by establishing a model of minimum review standards based on existing policies. Such a model for pre-dissemination review would still provide that responsibility for the reviews remains in the appropriate EPA Office or Region.

For the purposes of the Guidelines, EPA recognizes that pre-dissemination review procedures may include peer reviews and quality reviews that may occur at many steps in development of information, not only at the point immediately prior to the dissemination of the information.

8 Administrative Mechanisms for Correction of Information

8.1 What are EPA's Administrative Mechanisms for Affected Persons to Seek and Obtain Correction of Information?

EPA's Office of Environmental Information (OEI) manages the administrative mechanisms that enable affected persons to seek and obtain, where appropriate, correction of information disseminated by the Agency that does not comply with EPA or OMB Information Quality Guidelines. Working with the Program Offices, Regions, laboratories, and field offices, OEI will receive complaints (or copies) and distribute them to the appropriate EPA information owners. "Information owners" are the responsible persons designated by management in the applicable EPA Program Office, or those who have responsibility for the quality, objectivity, utility, and integrity of the information product or data disseminated by EPA. If a person believes that information disseminated by EPA may not comply with the Guidelines, we encourage the person to consult informally with the contact person listed in the information product before submitting a request for correction of information. An informal contact can result in a quick and efficient resolution of questions about information quality.

8.2 What Should be Included in a Request for Correction of Information?

Persons requesting a correction of information should include the following information in their Request for Correction (RFC):

- Name and contact information for the individual or organization submitting a complaint; identification of an individual to serve as a contact.
- A description of the information the person believes does not comply with EPA or OMB guidelines, including specific citations to the information and to the EPA or OMB guidelines, if applicable.
- An explanation of how the information does not comply with EPA or OMB guidelines and a recommendation of corrective action. EPA considers that the complainant has the burden of demonstrating that the information does not comply with EPA or OMB guidelines and that a particular corrective action would be appropriate.
- An explanation of how the alleged error affects or how a correction would benefit the requestor.
- An affected person may submit an RFC via any one of methods listed here:
  - **Internet** at http://www.epa.gov/oei/qualityguidelines
  - **E-mail** at quality.guidelines@epa.gov
  - **Fax** at (202) 566-0255

- **Mail** to *Information Quality Guidelines Staff*, Mail Code 28221T, U.S. EPA, 1200 Pennsylvania Ave., N.W., Washington, DC, 20460
- **By courier or in person** to *Information Quality Guidelines Staff*, OEI Docket Center, Room B128, EPA West Building, 1301 Constitution Ave., N.W., Washington, DC

8.3 When Does EPA Intend to Consider a Request for Correction of Information?

EPA seeks public and stakeholder input on a wide variety of issues, including the identification and resolution of discrepancies in EPA data and information. EPA may decline to review an RFC under these Guidelines and consider it for correction if:

- The request does not address information disseminated to the public covered by these Guidelines (see section 5.3 or OMB's guidelines). In many cases, EPA provides other correction processes for information not covered by these Guidelines.

- The request omits one or more of the elements recommended in section 8.2 and there is insufficient information for EPA to provide a satisfactory response.

- The request itself is "frivolous," including those made in bad faith, made without justification or trivial, and for which a response would be duplicative. More information on this subject may be found in the OMB guidelines.

8.4 How Does EPA Intend to Respond to a Request for Correction of Information?

EPA intends to use the following process:

- Each RFC will be tracked in an OEI system.

- If an RFC is deemed appropriate for consideration, the information owner office or region makes a decision on the request on the basis of the information in question, including a request submitted under section 8.2. Rejections of a request for correction should be decided at the highest level of the information owner office or region. EPA's goal is to respond to requests within 90 days of receipt, by 1) providing either a decision on the request, or 2) if the request requires more than 90 calendar days to resolve, informing the complainant that more time is required and indicate the reason why and an estimated decision date.

- If a request is approved, EPA determines what corrective action is appropriate. Considerations relevant to the determination of appropriate corrective action include the nature and timeliness of the information involved and such factors as the significance of the error on the use of the information and the magnitude of

the error. For requests involving information from outside sources, considerations may include coordinating with the source and other practical limitations on EPA's ability to take corrective action.

- Whether or not EPA determines that corrective action is appropriate, EPA provides notice of its decision to the requester.

- For approved requests, EPA assigns a steward for the correction who marks the information as designated for corrections as appropriate, establishes a schedule for correction, and reports correction resolution to both the tracking system and to the requestor.

OEI will provide reports on behalf of EPA to OMB on an annual basis beginning January 1, 2004 regarding the number, nature, and resolution of complaints received by EPA.

8.5 How Does EPA Expect to Process Requests for Correction of Information on Which EPA has Sought Public Comment?

When EPA provides opportunities for public participation by seeking comments on information, the public comment process should address concerns about EPA's information. For example, when EPA issues a notice of proposed rulemaking supported by studies and other information described in the proposal or included in the rulemaking docket, it disseminates this information within the meaning of the Guidelines. The public may then raise issues in comments regarding the information. If a group or an individual raises a question regarding information supporting a proposed rule, EPA generally expects to treat it procedurally like a comment to the rulemaking, addressing it in the response to comments rather than through a separate response mechanism. This approach would also generally apply to other processes involving a structured opportunity for public comment on a draft or proposed document before a final document is issued, such as a draft report, risk assessment, or guidance document. EPA believes that the thorough consideration provided by the public comment process serves the purposes of the Guidelines, provides an opportunity for correction of any information that does not comply with the Guidelines, and does not duplicate or interfere with the orderly conduct of the action. In cases where the Agency disseminates a study, analysis, or other information prior to the final Agency action or information product, it is EPA policy to consider requests for correction prior to the final Agency action or information product in those cases where the Agency has determined that an earlier response would not unduly delay issuance of the Agency action or information product and the complainant has shown a reasonable likelihood of suffering actual harm from the Agency's dissemination if the Agency does not resolve the complaint prior to the final Agency action or information product. EPA does not expect this to be the norm in rulemakings that it conducts, and thus will usually address information quality issues in connection with the final Agency action or information product.

EPA generally would not consider a complaint that could have been submitted as a timely comment in the rulemaking or other action but was submitted after the comment period. If EPA cannot respond to a complaint in the response to comments for the action (for example, because the complaint is submitted too late to be considered and could not have been timely submitted, or because the complaint is not germane to the action), EPA will consider whether a separate response to the complaint is appropriate.

generate and data or information generated by external parties, including States. State information, when submitted to EPA, may not be covered by these Guidelines, but our subsequent use of the information may in fact be covered. We note, however, that there may be practical limitations on the type of corrective action that may be taken, since EPA does not intend to alter information submitted by States. However, EPA does intend to work closely with our State counterparts to ensure and maximize the quality of information that EPA disseminates. Furthermore, one commenter stated that if regulatory information is submitted to an authorized or delegated State program, then the State is the primary custodian of the information and the Guidelines would not cover that information. We agree with that statement.

We also received comments regarding the use of labels, or disclaimers, to notify the public whether information is generated by EPA or an external party. We agree that disclaimers and other notifications should be used to explain the status of information wherever possible, and we are developing appropriate language and format.

A statement regarding Paperwork Reduction Act clearance submissions has been added in response to comment by OMB.

A.3.4 Influential Information

EPA received a range of comments on its definition of "influential." Below we provide a summary of the comments raised and EPA's response.

Several commenters generally assert that the definition is too narrow. Other commenters indicated that under EPA's draft definition, only Economically Significant actions, as defined in Executive Order 12866, or only Economically Significant actions and information disseminated in support of top Agency actions, are considered "influential." We disagree. To demonstrate the broad range of activities covered by our adoption of OMB's definition, we reiterate the definition below and include an example of each type of action, to illustrate the breadth of our definition. "Influential," when used in the phrase "influential scientific, financial, or statistical information," means that the Agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions. We will generally consider the following classes of information to be influential: information disseminated in support of top Agency actions; information disseminated in support of "economically significant" actions; major work products undergoing peer review; and other disseminated information that will have or does have a clear and substantial impact (i.e., potential change or impact) on important public policies or important private sector decisions as determined by EPA on a case-by-case basis. In general, influential information would be the scientific, financial or statistical information that provides a substantial basis for EPA's position on key issues in top Agency actions and Economically Significant actions. If the information provides a substantial basis for EPA's position, EPA believes it would generally have a clear and substantial impact.

Top Agency actions: An example of a top Agency action is the review of the National Ambient Air Quality Standards (NAAQS) for Particulate Matter. Under the Clean Air Act, EPA is to periodically review (1) the latest scientific knowledge about the effects on public health and public welfare (e.g., the environment) associated with the presence of such pollutants in the ambient air and (2) the standards, which are based on this science. The Act further directs that the Administrator shall make any revisions to the standards as may be appropriate, based on the latest science, that in her judgment are requisite to protect the public health with an adequate margin of safety and to protect the public welfare from any known or anticipated adverse effects. The standards establish allowable levels of the pollutant in the ambient air across the United States, and States must development implementation plans to attain the standards. The PM NAAQS were last revised in 1997, and the next periodic review is now being conducted.

"Economically significant" rules: An example of a rule found to be economically significant is the Disposal of Polychlorinated Biphenyls (PCBs) Final Rule. In 1998, EPA amended its rules under the Toxic Substances Control Act (TSCA), which addresses the manufacture, processing, distribution in commerce, use, cleanup, storage and disposal of PCBs. This rule provides flexibility in selecting disposal technologies for PCB wastes and expands the list of available decontamination procedures; provides less burdensome mechanisms for obtaining EPA approval for a variety of activities; clarifies and/or modifies certain provisions where implementation questions have arisen; modifies the requirements regarding the use and disposal of PCB equipment; and addresses outstanding issues associated with the notification and manifesting of PCB wastes and changes in the operation of commercial storage facilities. EPA would consider the information that provides the principal basis for this rule to be influential information.

Peer reviewed work products: An example of a major work product undergoing peer review is the IRIS Documentation: Reference Dose for Methylmercury. Methylmercury contamination is the basis for fish advisories. It is necessary to determine an intake to humans that is without appreciable risk in order to devise strategies for decreasing mercury emissions into the environment. After EPA derived a reference dose (RfD) of 0.0001 mg/kg-day in 1995, industry argued that it was not based on sound science. Congress ordered EPA to fund an National Research Council/National Academy of the Sciences panel to determine whether our RfD was scientifically justifiable. The panel concluded that the 0.0001 mg/kg-day was an appropriate RfD, based on newer studies than the 1995 RfD. The information in this document was evaluated, incorporated, and subjected to comment by the Office of Water, where it contributed in large part to Chapter 4 of *Drinking Water Criteria for the Protection of Human Health: Methylmercury* (EPA/823/R-01/001) January 2001. The peer review mechanism was an external peer review workshop and public comment session held on November 15, 2000, accompanied by a public comment period from October 30 to November 29, 2000.

Case-by-base determination – PBT Chemicals Rule: An example of a case-by-case determination is the Guidance Document for Reporting Releases and Other Waste

Regarding robustness checks, commenters were concerned that the EPA did not use the term "especially rigorous robustness checks." We have modified our Guidelines to include this term. Some commenters speculated on the ability of the Agency's Peer Review program to meet the intent of the Guidelines and were concerned about the process to rebut a peer review used to support the objectivity demonstration for disseminated information. Our Peer Review program has been subject to external review and we routinely verify implementation of the program. Affected persons wishing to rebut a formal peer review may do so using the complaint resolution process in these Guidelines, provided that the information being questioned is considered to be "disseminated" according to the Guidelines.

Regarding analytic results, some commenters indicated that the transparency factors identified by EPA (section 6.3 of the Guidelines) are not a complete list of the items that would be needed to demonstrate a higher degree of quality for influential information. EPA agreed with the list of four items that was initially provided by the OMB and recognizes that, in some cases, additional information regarding disseminated information would facilitate increased quality. However, given the variety of information disseminated by the Agency, we cannot reasonably provide additional details for such a demonstration at this time. Also, in regards to laboratory results, which were mentioned by several commenters, these Guidelines are not the appropriate place to set out for the science community EPA's view of what constitutes adequate demonstration of test method validation or minimum quality assurance and quality control. Those technical considerations should be addressed in the appropriate quality planning documentation or in regulatory requirements.

EPA has developed general language addressing the concept of reproducibility and may provide more detail after appropriate consultation with scientific and technical communities, as called for by OMB in its guidelines. We have already begun to consult relevant scientific and technical experts within the Agency, and also have planned an expedited consultation with EPA's Science Advisory Board (SAB) on October 1, 2002. Based on these initial consultations, EPA may seek additional input from the SAB in 2003. These consultations will allow EPA to constructively and appropriately refine the application of existing policies and procedures, to further improve reproducibility. In the interim, EPA intends to base the reproducibility of disseminated original and supporting data on commonly accepted scientific, financial, or statistical standards.

A.3.6 Influential Risk Assessment

General Risk Assessment

Risk assessment is a process where information is analyzed to determine if an environmental hazard might cause harm to exposed persons and ecosystems (paraphrased from Risk Assessment in the Federal Government, National Research Council, 1983). That is:

$$\text{Risk} = \text{hazard} \times \text{exposure}$$

For a chemical or other stressor to be "risky," it must have both an inherent adverse effect on an

organism, population, or other endpoint and it must be present in the environment at concentrations and locations that an organism, population, or other endpoint is exposed to the stressor. Risk assessment is a tool to determine the likelihood of harm or loss of an organism, population, or other endpoint because of exposure to a chemical or other stressor. To assist those who must make risk management decisions, risk assessments include discussions on uncertainty, variability and the continuum between exposure and adverse effects.

Risk assessments may be performed iteratively, with the first iteration employing protective (conservative) assumptions to identify possible risks. Only if potential risks are identified in a screening level assessment is it necessary to pursue a more refined, data-intensive risk assessment. The screening level assessments may not result in "central estimates" of risk or upper and lower-bounds of risks. Nevertheless, such assessments may be useful in making regulatory decisions, as when the absence of concern from a screening level assessment is used (along with other information) to approve the new use of a pesticide or chemical or to decide whether to remediate very low levels of waste contamination.

APPENDIX C – 3

Integrated Risk Information System (IRIS)

IRIS Public Meetings

- Hexavalent Chromium: Sep 19 & 25
- IRIS Bimonthly Meeting: Oct 23-24
- Mouse Lung Tumor Workshop: Oct 24-25

1 2 3 4

IRIS Most Viewed Chemicals

Full List of IRIS Chemicals

Acrylamide	Cadmium	Mercury, elemental
Arsenic, inorganic	Chromium (VI)	Methylmercury (MeHg)
Benzene	1,4-Dioxane	Polychlorinated biphenyls (PCBs)
Bisphenol A	Formaldehyde	Silver

EPA's Integrated Risk Information System (IRIS) is a human health assessment program that evaluates information on health effects that may result from exposure to environmental contaminants. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database is web accessible and contains information on more than 550 chemical substances. Learn more.

What's New in IRIS

- 09/30/13: EPA announces the availability of the final IRIS Toxicological Review and IRIS Summary for Methanol (Noncancer). The Interagency Science Discussion Draft of the Methanol (Noncancer) IRIS assessment was also released. New!
- 09/30/13: EPA announces an extension of the public comment period for the draft document, *Toxicological Review of Benzo[a]pyrene (Public Comment Draft)*. (Deadline for comment is November 21st) New!
- 09/20/13: EPA announces the availability of the final IRIS Toxicological Review and IRIS Summary for 1,4-Dioxane. The Interagency Science Discussion Draft of the 1,4-Dioxane IRIS assessment (with Inhalation Update) was also released. New!
- 08/28/13: EPA's Science Advisory Board (SAB) announces a request for nominations of experts to augment the SAB Chemical Assessment Advisory Committee for the review of the draft IRIS Toxicological Reviews of Ammonia and Trimethylbenzenes (Revised External Review Drafts), and the draft Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Revised External Review Draft) (Deadline for nominations is September 18th)
- 08/28/13: EPA announces an extension of the public comment period for the draft document, Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide (Revised External Review Draft). (Deadline for comment is October 11th)
- 08/27/13: EPA announces the availability of the final IRIS Toxicological Review and IRIS Summary for Biphenyl. The Interagency Science Discussion Draft of the Biphenyl IRIS assessment was also released.

See more recent additions

Recent Final Assessments

- Methanol New! (09/30/13)
- 1,4-Dioxane New! (09/20/13)

Draft Assessments under External Peer Review

- Ammonia – Revised (08/28/13)
- Trimethylbenzenes – Revised (08/28/13)
- Benzo[a]pyrene (08/21/13)

- Biphenyl (08/27/13)
- Tetrahydrofuran (02/21/12)
- 2,3,7,8-Tetrachlorodibenzo-p-dioxin (02/17/12)

See the full list of Final Assessments

- Ethylene Oxide (inhalation cancer) - Revised (07/29/16)

See full list of IRIS Draft Reports

Recent Additions
Basic Information
IRIS Calendar
IRIS Process
A to Z List of IRIS Substances

Advanced Search
Compare IRIS Values
IRIS Guidance
Download IRIS

IRISTrack
Site Help & Tools
Archived Drafts & Comments
Related Links

Top 3 Tasks

- Recent Additions
- IRIS Process
- Contacting the IRIS Hotline

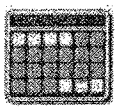
Search IRIS by Keyword

GO

IRIS Summaries/Toxicological Reviews
Entire IRIS Website

Perform an advanced search

IRIS Calendar



- View the IRIS Calendar
- IRIS Public Meetings
- Receive notifications of IRIS Recent Addition items

IRIS Quick Links

- IRIS Basics - 101
- IRIS Guidelines
- IRIS Frequent Questions
- IRIS Agenda & Literature Searches
- IRISTrack | What is IRISTrack?
- IRIS Glossary
- Download IRIS
- Sign up for the IRIS Mailing List

Last updated on Monday, September 30, 2013

APPENDIX C – 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 21 2012

OFFICE OF
ENVIRONMENTAL INFORMATION

Mr. Gregory Dolan
Executive Director – Americas/Europe
Methanol Institute
124 West Street South
Suite 203
Alexandria, VA 22314

Dear Mr. Dolan:

I am providing you with another status update on the EPA response to your July 2010, Information Quality Guidelines Request for Correction (RFC 10005). As noted in our June 2011 interim response, EPA placed the IRIS Methanol Toxicological Review (Cancer) on hold. The external peer review draft assessment noted in your Request for Correction containing the methanol cancer analysis has now been archived on the IRIS website[1]. Further development of an IRIS methanol assessment for cancer will follow the established IRIS process, which includes opportunities for public comment.

We will provide a final response or a status update in 90 business days.

Sincerely,

for

Monica D. Jones,
Acting Director, Quality Staff

[1] http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=56521

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 24 2012

OFFICE OF
ENVIRONMENTAL INFORMATION

Gregory Dolan, Executive Director – Americas/Europe
Methanol Institute
124 West Street South
Suite 203
Alexandria, VA 22314

Dear Mr. Dolan:

The December 2009 Integrated Risk Information System (IRIS) Toxicological Review of Methanol (External Review Draft)[1] which is the subject of the Methanol Institute's information quality guidelines Request for Correction (RFC 10005)[2] has been archived.[3]

In March 2012, EPA announced that it would no longer rely on certain data[4] that were used in the December 2009 draft Toxicological Review of methanol to characterize the carcinogenic potential of methanol. Since the document upon which the Methanol Institute's Request for Correction is based is no longer being considered, As a result, EPA plans to close the associated RFC.

The IRIS assessment development process[5] offers multiple opportunities for the public, including the Methanol Institute, to provide input on draft assessments. The current status of the cancer and non-cancer methanol assessments is available on the IRISTrack website[6] and will be updated as new information becomes available.

If you have questions about the decision to close your RFC, please contact me at (202) 564-1641. If you have questions about the IRIS assessment for methanol, please contact Jeffrey Gift at (919) 541-4828.

Sincerely,

Monica D. Jones

Monica D. Jones, Director
Quality Staff

---

[1] IRIS Toxicological Review of Methanol (External Review Draft), U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-09/013, December 2009.
[2] RFC 10005, July 2010 (http://epa.gov/quality/informationguidelines/documents/RFC10005.pdf)
[3] http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=506440
[4] See the Ramazzini update - http://www.epa.gov/IRIS/ramazzini.htm
[5] http://www.epa.gov/iris/process.htm
[6] http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=225977

cc: Lek Kadeli, Acting Assistant Administrator,
Office of Research and Development
Malcolm D. Jackson, Assistant Administrator and Chief Information Officer,
Office of Environmental Information (2810A)
Jeff Gift, RTP Division, Office of Research and Development (B243-01)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 24 2012

OFFICE OF
ENVIRONMENTAL INFORMATION

Lynn L. Bergeson, Managing Director
Bergeson & Campbell, P.C.
1203 Nineteenth Street, N.W.
Suite 300
Washington, D.C. 20036-2401

Dear Ms. Bergeson:

The February 2010, Integrated Risk Information System (IRIS) Toxicological Review of Inorganic Arsenic (External Review Draft)[1] which is the subject of the Organic Arsenical Products Task Force (OAPTF) and Wood Preservative Science Council (WPSC) Request for Correction (RFC 10004)[2] has been archived. As a result, EPA plans to close this RFC.

EPA plans to initiate the development of a new Toxicological Review of inorganic arsenic in the near future[3]. Information on the new schedule will be available on the IRIS Substance Assessment Tracking System (IRISTrack[4]) as it becomes available.

The IRIS assessment development process[5] offers multiple opportunities for the public, including OAPTF and WPSC, to provide input on draft assessments. In addition, the OAPTF and WPSC will be able to provide comments on scientific issues related to the evaluation of inorganic arsenic toxicity during a public workshop, which will be hosted by the National Academy of Sciences (NAS). When the draft IRIS assessment is completed, it will be provided to the NAS for external peer review.

If you have questions about the decision to close your RFC, please contact me at (202) 564-1641. If you have questions about the IRIS assessment for inorganic arsenic, please contact Reeder Sams at (919) 541-0661.

Sincerely,

Monica D Jones

Monica D. Jones, Director
Quality Staff

---

[1] IRIS Toxicological Review of Inorganic Arsenic (External Review Draft), U.S. Environmental Protection Agency, EPA/635/R-10/001, Washington, DC, February 2010. (http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=494787)
[2] RFC 10004, June 2010 (http://epa.gov/quality/informationguidelines/documents/10004.pdf)
[3] http://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=225977
[4] http://cfpub.epa.gov/ncea/iristrac/
[5] http://www.epa.gov/iris/process.htm

cc: Lek Kadeli, Acting Assistant Administrator,
Office of Research and Development
Malcolm D. Jackson, Assistant Administrator and Chief Information Officer,
Office of Environmental Information (2810A)
Reeder Sams, Acting Deputy Division Director
RTP Division, Office of Research and Development (B-243-01)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 8 2011

OFFICE OF
ENVIRONMENTAL INFORMATION

Lynn L. Bergeson, Managing Director
Bergeson & Campbell, P.C.,
1203 Nineteenth Street, N.W.
Suite 300
Washington, D.C. 20036-2401

Dear Ms. Bergeson:

I am providing you with a status update on the June 14, 2010, Information Quality Guidelines (IQG) Request for Correction (RFC 10004), which was submitted to the U.S. Environmental Protection Agency (EPA), on behalf of the Organic Arsenical Products Task Force (OAPTF) and the Wood Preservative Science Council (WPSC). This RFC is related to the Integrated Risk Information System (IRIS) Toxicological Review of Inorganic Arsenic.

EPA expects to address the information quality concerns raised in your RFC through the IRIS peer review and public comment-response process. The SAB peer review for the Toxicological Review of Inorganic Arsenic was completed earlier this year[1] and the Agency is considering the recommendations and making revisions to the document. A summary of the Agency's planned responses to the SAB is available on the web[2]. OAPTF and WPSC RFC comments that were not specifically addressed by the SAB will be addressed by EPA in the final Toxicological Review and documented in the appendices.

We will update you on the status of the RFC response within 90 business days.

Sincerely,

Monica D. Jones, Acting Director
Quality Staff

[1] http://yosemite.epa.gov/sab/sabproduct.nsf/WebReportsbyYearBOARD!OpenView&Start=1&Count=800&Collapse=1#1
[2] http://yosemite.epa.gov/sab/sabproduct.nsf/9FCEE4E20ABD6EB48525784600791AC2/$File/EPA-SAB-11-003_Response_05-20-2011.pdf

APPENDIX C – 5

EXCERPTS

REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE

Committee to Review EPA's Draft IRIS Assessment of Formaldehyde

Board on Environmental Studies and Toxicology

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

THE NATIONAL ACADEMIES PRESS 500 Fifth Street, NW Washington, DC 20001

NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This project was supported by Contract EP-C-09-003 between the National Academy of Sciences and U.S. Environmental Protection Agency. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the authors and do not necessarily reflect the view of the organizations or agencies that provided support for this project.

International Standard Book Number-13: 978-0-309-21193-2
International Standard Book Number-10: 0-309-21193-X

Additional copies of this report are available from

The National Academies Press
500 Fifth Street, NW
Box 285
Washington, DC 20055

800-624-6242
202-334-3313 (in the Washington metropolitan area)
http://www.nap.edu

Printed in the United States of America.